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IN THE

Supreme Court of the United States

OCTOBER TERM, 1944

No. [redacted] 316

RALADAM COMPANY, as Claimant of 62 Packages, more or less, of Marmola Prescription Tablets,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SEVENTH CIRCUIT AND BRIEF IN SUPPORT THEREOF

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No.

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UNITED STATES OF AMERICA,
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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SEVENTH CIRCUIT

To the Honorable Harlan F. Stone, Chief Justice of the United States, and the Associate Justices of the Supreme Court of the United States:

Your petitioner respectfully shows:

STATEMENT OF THE MATTER INVOLVED

These proceedings were commenced by the Government in the United States District Court for the Western District of Wisconsin, on April 11, 1939 (R. 1), for the condemnation of 62 packages, more or less, of a drug product called Marmola on the charge that it is misbranded (R.

5-7) under Sec. 502(j) of the Federal Food, Drug and Cosmetic Act of 1938 [52 Stat. 1040, c. 675; 21 U.S.C., Sec. 301 et seq.]*, an official pamphlet copy of which is hereto attached as an appendix for the Court's convenience. Sec. 502(j) of the Act [21 U.S.C., Sec. 352(j)] provides as follows:

> "Sec. 502. A drug or device shall be deemed to be misbranded—
>
> "(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

The Raladam Company, as the longtime owner and distributor of Marmola (R. 18), intervened as claimant (R. 3-5), and, issue having been joined (R. 15), the case was tried without a jury (R. 20), upon the express stipulation that: "The only ingredient of Marmola Prescription Tablets that is involved in this action is the ½ grain of desiccated thyroid contained in each tablet" (R. 19).

The Marmola labeling recommends it *solely* as a treatment for *adults* with obesity *caused by hypothyroidism* but who are otherwise normal and healthy. Persons with any other disease or abnormal condition are warned not to take it (R. 8). The daily dosage in which Marmola is recommended is 4 tablets a day, each of which contains ½ grain of desiccated thyroid, as aforesaid, making a

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*The Government also counted on Secs. 502(a) and 201(n) of the Act [21 U.S.C., Secs. 352(a) and 321(n)], the effective date of which was expressly postponed by Sec. 902(a) thereof [21 U.S.C., Sec. 392(a)] until "twelve months after the date of its enactment," *viz.*, until June 25, 1939, and, therefore, until after the date of the commencement of these proceedings. The theory advanced by the Government for thus seeking to prematurely invoke Secs. 502(a) and 201(n) was that they were needed to aid in the enforcement of Sec. 502(j). However, even if there were any merit in this contention, the fundamental question in the case, *viz.*, whether Marmola is misbranded under Sec. 502(j), is left unchanged for, unless there is a violation of Sec. 502(j), no aid in its enforcement is needed.

total recommended daily dosage of 2 grains of desiccated thyroid a day; and the Marmola labeling further recommends that it be taken for no longer than "sixty to ninety days—if needed that long" (R. 8-9).

The record in this case discloses that the Marmola labeling, in recommending an average dosage of 2 grains of desiccated thyroid for adults with obesity caused by hypothyroidism, but who are otherwise normal and healthy, is in accord with approved medical practice. The medical witnesses who testified for the Government were in agreement that desiccated thyroid is a "specific" for hypothyroidism (R. 86, 88-9, 188-9, 281, 535-6, 586, 613, 630-1, 853, 860-1, 865). According to Dr. Carlson, who is the official consultant of the Food and Drug Administration on such matters (R. 897): "It is *indispensable* at the present time in therapy of hypothyroidism" (R. 902).

Furthermore, virtually all of the medical witnesses who testified for the Government recognized hypothyroidism as being either a cause or contributing factor in the production of obesity (R. 24, 42, 112-13, 186-87, 205, 242, 278-80, 428, 432, 536, 615, 865). Dr. Short, one of the most prominent of the Government's medical witnesses, and a teacher (R. 33) and specialist in this field (R. 35), said: "I don't think anybody would deny" that hypothyroidism is a predisposing or contributing factor in the production of obesity (R. 113). Likewise, Dr. Severinghaus, another leading Government witness, said: "Certainly," when asked whether he recognized hypothyroidism as a cause of obesity (R. 865).

As a result of the foregoing, desiccated thyroid is "widely used" (R. 88) by the medical profession in the treatment of obesity caused or contributed to by hypothyroidism (R. 54, 58, 80, 84-5, 86, 88, 109, 113, 172, 186, 189, 191, 383, 384, 399, 418-9, 420, 426-7, 429, 500, 614-5, 637, 641-2, 643, 682, 683, 856-7, 858, 866-7) and, as has been pointed out hereinabove, this is the very condi-

tion and, in fact, "only" condition that Marmola is recommended for in its labeling, as aforesaid (R. 8).* In addition, the "generally established" (R. 115) average dosage in which desiccated thyroid is prescribed for this condition by the Medical profession *is the same* as the dosage recommended in the Marmola labeling, *viz.*, 2 grains per day (R. 55, 87, 115, 248, 544, 608, 639, 647, 686, 710-11, 892).** Finally, such a dosage is relatively small compared to that which had been prescribed by many of the doctors who testified for the Government (R. 89, 131, 138, 140, 149-50, 194, 393-4, 487, 610, 686-7, 892-3), two of the most prominent of whom had prescribed it in doses up to 50 grains (R. 609, 618, 711, 714) presumably without fear of doing their patients any harm.

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*Furthermore, it should be noted, in this connection, that although Dr. Severinghaus was apparently willing to deny the propriety of using desiccated thyroid in the treatment of obesity, *generally*, when testifying against a patent medicine (R. 866-7), his recent book on "Endocrine Therapy In General Practice," which he gave as one of his qualifications for testifying as an expert in this field (R. 779), contains the following pertinent statement (R. 866):

> "In some patients obesity is lost slowly *except on the use of thyroid* without diet, even though they have a normal basal metabolism and no other evidence of hypothyroidism. For such persons *the use of thyroid* is helpful and constitutes a sort of passive exercise." (Italics ours)

**Of course it is true that the tolerance of all persons for desiccated thyroid is not the same, as is pointed out in the Marmola labeling (R. 9). However, it is approved medical practice to start out with an average dose, and *cut it in half* if it proves to be too high, as disclosed by the appearance of unpleasant and readily recognizable symptoms of overdosage (R. 89-90, 152, 158, 173, 192, 430, 590, 642-3, 892). The Marmola labeling follows this practice by instructing users that: "If any unpleasant effects are experienced stop taking Marmola until they disappear, then resume taking one-half of the former dosage or consult a physician" (R. 9). Moreover, it should be noted that the symptoms which disclose a person's intolerance for a given dosage of desiccated thyroid are mild and purely transitory (R. 89-91, 101, 104, 111, 157-8, 159, 160, 590, 806-7). They appear before any real harm has been done (R. 118), and disappear promptly when the medication is discontinued or the dosage lowered (R. 24, 90-1, 97, 101, 105, 111, 159, 161, 200-1, 202-3, 590, 612, 862-3). In fact, this is the theory upon which specialists in this field, like Dr. Short, are practicing medicine (R. 91).

To summarize the material parts of the record herein, it has been established by the Government's proof alone that the Marmola dosage and directions for use are in accord with what the medical profession itself prescribes. This is so, because the *sole* condition for which Marmola is recommended in its labeling is the very condition for which it is "widely used" by the medical profession, as being the "specific" and "indispensable" treatment for hypothyroidism and obesity so caused or contributed to. Furthermore, the dosage of desiccated thyroid recommended in the Marmola labeling is not only the "generally established" *average* dosage prescribed in such treatment by specialists in this field, but well within the maximum dosage they have prescribed presumably without fear of endangering the health of their patients.

In view of the foregoing, it seems clear that there is no basis for the decision of the Circuit Court of Appeals for the Seventh Circuit herein that Marmola is "dangerous to health" and misbranded within the meaning of a provision of the statute—like Sec. 502(j)—which speaks in terms of *labeling* and makes purely *labeling* requirements. In other words, the fact that Marmola can be taken *according to* the directions and instructions in its labeling without danger to health (as defined by recognized medical standards), would seem to relieve it of any charge of being *misbranded* under a *labeling* provision like Sec. 502(j).

However, the Government takes the position and has tried this case on the theory that Sec. 502(j) is designed to protect the public not only from those dangers to health *created by improper labeling*, but also from the potential dangers *inherent* in self-medication, *per se*. These dangers arise primarily from the possibility of a layman, untrained in medical science, making a mistake in *self-diagnosis* and getting into difficulty through taking a *properly labeled* drug under the mistaken impression that he is one of those for whom it is recommended in its labeling.

This being the Government's construction of Sec. 502(j), it devoted its efforts on the trial of this case to the introduction of evidence—over the repeated and continuing objection of your petitioner regarding its materiality (R. 27-8, 51, 178, 183, 439-40, 755, 758, 769, 771)—that laymen, who are untrained in medical science, may have certain *latent* diseases or conditions *of which they are unaware* and incompetent to diagnose; that the use of desiccated thyroid in the presence of such latent diseases or conditions is contra-indicated because it may precipitate an active stage thereof; and that as a result of these potential dangers *inherent* in self-medication with desiccated thyroid, *per se*, laymen should not be permitted to use it *except* upon the prescription and under the continuous supervision of a competent physician.*

Based on evidence of this kind, the trial Court decided that Marmola was "dangerous to health" and *misbranded* within the meaning of Sec. 502(j) because it cannot be

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*This proof consisted of the opinion testimony of a number of expert witnesses (R. 32-125, 126-70, 170-216, 216-314, 384-99, 417-42, 478-553, 556-79, 580-634, 636-40, 640-8, 668-727 & 850-60, 728-54, 777-822 & 860-96, 824-50 & 896-903); testimony concerning the results of a poll taken of various doctors throughout the country by the Food and Drug Administration to determine the so-called consensus of medical opinion regarding the advisability of permitting the public to self-medicate with desiccated thyroid in the Marmola dosage (R. 755-68, 769-76, 1197-1258); and the testimony of half a dozen lay witnesses concerning the unfavorable reactions allegedly suffered by themselves or their relatives from taking desiccated thyroid in the Marmola dosage (R. 314-29 & 352-6, 413-7, 442-55, 469-74, 649-58, 658-67). The *im*materiality of this testimony, even under the Government's theory of the case, is clearly revealed by the fact that the first of these witnesses had taken desiccated thyroid—not for self-medication, but under the supervision of her own physician (R. 319); and by the fact that all of them had taken Marmola *in violation* of one or more of the directions and instructions in the Marmola labeling concerning maximum dosage (R. 663-4), maximum duration of treatment (R. 353, 665), or discontinuing its use in the face of unpleasant symptoms (R. 415, 445, 470-1, 652, 663-5). Hence, none of these persons got into difficulty through taking Marmola *as prescribed* in its labeling (R. 9), the statement of the Circuit Court of Appeals for the Seventh Circuit to the contrary notwithstanding; and, more significant still, their failure to follow such directions could have been readily avoided by them, for it was in no way attributable to a mistake in self-diagnosis.

taken in the recommended dosage in perfect safety in the face of a *mistake in self-diagnosis*, which might result in its use *in violation* of the directions and instructions in the labeling thereof. Stated succinctly, the basis of the trial Court's decision herein *is not* that the use of Marmola *as prescribed* is "dangerous to health" but that its use *otherwise* than as prescribed may be. The pertinent parts of the trial Court's decision so holding (reported in 48 F. *Supp.* 878) read as follows (R. 1313, 1314):

> "Any drug, which for safety in its use requires *diagnosis* and *evaluation*, and when taken in the dosage and with the frequency recommended and suggested in its labeling, may expose the users to disease and pain, is dangerous to health. Marmola is such a drug. In it there is an *inherent* and *potential* danger that may reasonably be expected to attend its use when one considers that it will be used by the strong, the *weak*, the *old*, the *young*, the well, and the *sick*, without *first* having a *physical examination* or a *diagnosis* of their condition by a *competent physician*.
>
> * * * * *
>
> "* * * It places a duty upon the user to make *a self-diagnosis* to determine if he is suffering from hypothyroidism. The layman lacks familiarity with medical terminology. He has little or no knowledge of medical science, and does not possess that skill and learning required to determine whether he is suffering from hypothyroidism. * * *
>
> * * * * *
>
> "The administration of thyroid tablets in Marmola dosages is a dangerous procedure, and should not be undertaken *without a thorough examination of the prospective user by a competent physician, and then only under the supervision of the doctor.*" (Italics ours)

A decree of condemnation having been entered in accordance with the foregoing decision on April 7, 1943, (R.

1327), an appeal was taken therefrom to the Circuit Court of Appeals for the Seventh Circuit on June 22, 1943 (R. 1328), on the following grounds, among others (R. 1329-37):

1. That the *misbranding* provisions of the Federal Food, Drug and Cosmetic Act—like Sec. 502(j)—are purely *labeling* provisions the violation of which is to be determined accordingly; and, hence, it follows that a drug which can be taken as *prescribed* in its *labeling* without danger to health (as defined by recognized medical standards) is not *misbranded* thereunder.

2. That, being purely a *misbranding* provision designed to remove the dangers of self-medication *created by improper labeling*, *Sec.* 502(j) was not designed to prevent self-medication with effective dosages of useful drugs like desiccated thyroid merely because of the potential dangers *inherent* therein, *per se*.

3. That Sec. 502(f) of the statute, by requiring the *labeling* of all drugs to contain warnings of the potential dangers *inherent* in self-medication, *per se*, recognizes the propriety of labeling drugs for self-medication in spite of the presence of such dangers.

4. That Sec. 502(e) of the statute, by making express requirements concerning the labeling of "active," *viz.*, effective dosages of desiccated thyroid for self-medication, recognizes the propriety of labeling it in such doses for such use.*

5. That, although Sec. 503(b) of the statute exempts drugs dispensed on a doctor's prescription from certain of its misbranding provisions, like

*This is so because Sec. 503(b) of the statute exempts drugs dispensed on a doctor's prescription from the requirements of Sec. 502(e), thereby making it applicable to the drugs listed therein *solely* when they are labeled for *self-medication*.

Sec. 502(e), as aforesaid, it does not exempt drugs *so* dispensed from Sec. 502(j); with the result that Sec. 502(j) cannot be construed to prevent the labeling of desiccated thyroid—in effective dosages—for *self-medication*, while permitting its continued labeling for use in such dosages on a doctor's prescription.

6. That, if any doubt remains that Sec. 502(j) is not designed to prevent self-medication with effective dosages of useful drugs, like desiccated thyroid, it is finally set to rest by the *legislative history* of the statute, which clearly discloses that Sec. 502(j) and the other *misbranding* provisions of the statute were not intended to make any useful drug unavailable for self-medication, providing it is *properly labeled*, according to recognized medical standards.

7. That the trial Court's construction of Sec. 502(j) should be avoided because it casts grave doubt on its constitutionality, as being (1) an improper interference by Congress in a matter of purely local concern; (2) an unwarranted attempt to prohibit the right of citizens of this country to medicate themselves, without the existence of any *public* necessity for so doing; and (3) a provision the violation of which entails severe penalties and forfeitures without furnishing any fair or ascertainable standard for gauging compliance therewith in advance of prosecution and punishment.

8. That there is no proof in the record in this case to support a finding that desiccated thyroid in the Marmola dosage is "dangerous to health" (as defined by recognized medical standards), if taken *according to* the directions and instructions in the Marmola labeling—all the proof being to the contrary; and this is the test to be applied in determining whether Marmola is misbranded under

> Sec. 502(j), when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly.

Following the hearing on appeal, the Circuit Court of Appeals for the Seventh Circuit handed down its decision on May 4, 1944 (R. 1353-9), affirming the decision of the trial Court, for *the same fundamental reasons* as those adopted by the trial Court as the basis of its decision herein, as aforesaid. That this is so is apparent upon an analysis of the opinion of the Circuit Court of Appeals (officially reported in 142 F. (2nd) 107), which is epitomized in one of the concluding sentences thereof as follows (R. 1358):

> "It devolved upon the trial court to determine *only* whether it was proved that the drug is dangerous to the public health *at large* if used as recommended [*viz.*, in the dosage recommended] by its vendors."

A moment's reflection will disclose that it is impossible to recommend an effective dosage of any useful drug, known to *materia medica*, that will be *universally* safe under every condition of use and *misuse** attributable to a mistake in *self-diagnosis*; and that self-diagnosis is *a necessary precursor* of all self-medication. Consequently, it follows that, if the test of whether a drug is "dangerous to health" and misbranded under Sec. 502(j) is that laid down in the decision of the trial Court and the Circuit Court of Appeals for the Seventh Circuit affirming the same, then virtually all drugs offered to the public for self-medication are misbranded thereunder, *per se*,

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*That this is true is well recognized by the medical profession (R. 203-4, 440-1, 712), including Dr. Brimmer (R. 1216, 1236), Senior Medical Officer of Federal Food and Drug Administration (R. 1197-8); and has been judicially recognized by this Court in *Coca Cola Co. v. Koke Co.*, 254 U.S. 143, 145; and the Circuit Court of Appeals for the Sixth Circuit in *Raladam Co. v. Fed. Trade Comm.*, 42 F. (2nd) 430, 433-4.

i.e., regardless of the propriety of their labeling; and what has always, heretofore, been regarded as the inalienable right of a citizen of this country to medicate himself with effective dosages of efficacious drugs, that are properly labeled, has become non-existent.

From this it follows that the real question presented by this case is whether *the user* of a proprietary medicine, containing the "generally established" (R. 115) average dosage prescribed by the medical profession of a useful drug—like desiccated thyroid—is prevented by Sec. 502(j) from *himself determining* the desirability or necessity of such use *in his particular case*. If *the user* has such a right under Sec. 502(j)—and it is submitted that he has when it is properly construed—then, *a fortiori*, there can be no violation of Sec. 502(j) in making available to him a preparation with a label showing what it contains and how it should be used—all in accordance with recognized medical standards.

JURISDICTION

(a) The statutory provision which sustains the jurisdiction of this Court to review the decision of the Circuit Court of Appeals for the Seventh Circuit affirming the decision of the trial Court herein is Section 240(a) of the Judicial Code as amended by the Act of February 13, 1925 [43 Stat. 938, c.229; 45 Stat. 54, c.14; 48 Stat. 926, c.426; 28 U.S.C., Sec. 347].

(b) The statute involved in these proceedings is the Federal Food, Drug and Cosmetic Act of 1938 [52 Stat. 1040, c.675; 21 U.S.C., Secs. 301 et seq.], and particularly Sec. 502(j) thereof [21 U.S.C., Sec. 352(j)] which reads as follows:

> "Sec. 502. A drug or device shall be deemed to be misbranded—
>
> "(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

(c) The decision of the Circuit Court of Appeals for the Seventh Circuit, of which review is sought, was filed and judgment entered thereon on May 4, 1944 (R. 1353-9). This case falls within the jurisdictional provision relied on for the reasons stated, *infra*, pp. 14-18, under the heading "Reasons Relied On For Allowance Of The Writ."

QUESTIONS PRESENTED

I. In view of the applicable decision of this Court in *McDermott v. Wisconsin*, 228 U.S. 115, 133, is Sec. 502(j) purely a *labeling* provision the violation of which is to be determined accordingly—thereby making "the *label* is the *means* of *vindication* and the *basis* of *punishment*" in deciding whether a drug is misbranded thereunder; *or* is the test of *misbranding* under Sec. 502(j) whether there are any potential dangers *inherent* in *self-medication* with *effective* dosages of a drug?

II. In view of the wording of the other misbranding provisions of the statute in *pari materia* with Sec. 502(j), and its legislative history, is Sec. 502(j) subject to a construction which will prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for *self-medication*, because of the potential dangers *inherent* therein, and, at the same time, permit their continued labeling for use on a doctor's prescription?

III. Does the construction placed on Sec. 502(j) by the decision of the Circuit Court of Appeals for the Seventh Circuit, affirming the decision of the trial Court herein, cast grave doubt upon its constitutionality?

IV. Does the record herein contain evidence which—as a matter of law—will support a finding that Marmola is *misbranded* under Sec. 502(j), when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly?

REASONS RELIED ON FOR ALLOWANCE OF THE WRIT

1. The decision of the Circuit Court of Appeals for the Seventh Circuit *herein* is in conflict with an applicable decision of this Court in *McDermott v. Wisconsin*, 228 U.S. 115, defining the *purpose* and *scope* of "misbranding" provisions—such as Sec. 502(j) of the Federal Food, Drug and Cosmetic Act. The pertinent parts of this Court's opinion, in this connection, are found on pages 130, 131 and 132-3 thereof and read as follows:

> "* * * Within the limitations of its right to regulate interstate commerce, Congress manifestly is aiming at the contents of the package as it shall reach the consumer, for whose protection the act was primarily passed, and *it is the branding* upon the package which contains the article intended for consumption itself *which is the subject-matter of regulation.* * * *
>
> "The *object* of the statute is to prevent *the misuse of the facilities of interstate commerce* in *conveying to* and *placing before* the consumer *misbranded* and adulterated articles of medicine or food, and in order that its protection may be afforded to those who are intended to receive its benefits the brands regulated must be upon the packages intended to reach the purchaser. This is *the only practical or sensible construction of the act*, and, for the reasons we have stated, we think the requirements of the act *as so construed* clearly *within the powers of Congress* over the facilities of interstate commerce, and such has been the construction generally placed upon the act by the Federal courts. (Citing cases)
>
> * * * * * *
>
> "The *label* upon the unsold article *is* in the one case *the evidence* of the shipper that he has complied

> with the act of Congress, while in the other, by its misleading and false character, it furnishes the proof upon which the Federal authorities depend to reach and punish the shipper and to condemn the goods. If truly labeled within the meaning of the act his goods are immune from seizure by Federal authority; if the label is false or misleading within the terms of the law the goods may be seized and condemned. In other words *the label* is the *means of vindication* or the *basis of punishment* in determining the character of the interstate shipment dealt with by Congress. * * *" (Italics ours)

As hereinabove pointed out (*supra*, pp. 6-10), the Circuit Court of Appeals for the Seventh Circuit, in affirming the decision of the trial Court herein, did not apply a *labeling* test in determining that Marmola is misbranded under Sec. 502(j) of the Federal Food, Drug and Cosmetic Act. Instead, the test applied was whether Marmola is *inherently* dangerous for self-medication, *per se*, regardless of the propriety of its labeling. Inasmuch, as such a test does not make the Marmola *labeling* "the means of vindication or the basis of punishment" in determining whether Marmola is misbranded under Sec. 502(j), the decision and judgment of the Circuit Court of Appeals for the Seventh Circuit herein is clearly in conflict with the applicable decision of this Court in *McDermott v. Wisconsin, supra.* As a result it is submitted that this petition for a writ of certiorari to review the same should be granted for this reason alone (Rule 38, Sec. 5(b) of the Rules of this Court; *San Giorgio I v. Rheinstrom Co.*, 294 U.S. 494, 495-6; *National Labor Relations Board v. Newport News Co.*, 308 U.S. 241, 244; *Ford Motor Co. v. Beauchamp*, 308 U.S. 331, 332; *Yearsley v. Ross Construction Co.*, 309 U.S. 18, 20; *Helvering v. Fitch*, 309 U.S. 149, 150; *Russell v. Todd*, 309 U.S. 280, 284; *Helvering v. Leonard*, 310 U.S. 80, 91; *West India Oil Co. v. Domenech*, 311 U.S. 20, 24; *Department of Treasury of Indiana v. Wood Preserving Corp.*, 313 U.S. 62, 63; *D'Oench, Duhme & Co. v. Federal Deposit Insurance Corp.*, 315 U.S. 447, 455).

2. This case presents an important question of federal law which has not been, but should be, settled by this Court. As has been pointed out (*supra*, pp. 10-11), the potential dangers *inherent* in the use of *effective* dosages of desiccated thyroid for self-medication are *inherent* in self-medication with all useful drugs to a varying degree. Inasmuch as the construction placed on Sec. 502(j), by the Circuit Court of Appeals for the Seventh Circuit herein, makes the presence or absence of such dangers the criterion of whether a drug is misbranded thereunder, it follows that virtually all drugs are misbranded thereunder, *per se*, if they are labeled in effective dosage for use by the public for self-medication.

This being so, the important question of federal law which has not been, but should be, settled by this Court is: Can Sec. 502(j) be construed in such a manner as to make virtually all useful drugs known to *materia medica*, including desiccated thyroid, unavailable to the public in *effective* dosages for self-medication, *viz.*, except on a doctor's prescription, (1) in view of its wording, the wording of other misbranding provisions of the statute in *pari materia* therewith, and its legislative history, and (2) without casting grave doubt upon its constitutionality?

The final determination by this Court of this question of the proper construction and application of a new federal statute, promulgated for the public welfare, is clearly of great importance not only to your petitioner, but to those engaged in administering and enforcing the statute; and, in a most vital sense, to the public at large. Hence, it is submitted that this furnishes an additional reason which should impel this Court to grant this petition (Rule 38, Sec. 5(b) of the Rules of this Court; *Worcester County Trust Co. v. Riley*, 302 U.S. 292, 296; *West India Oil Co. v. Domenech*, 311 U.S. 20, 24; *Miles v. Illinois Central R. Co.*, 315 U.S. 698, 700-1; *O'Donnell v. Great Lakes Dredge & Dock Co.*, 318 U.S. 36, 38; *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, 223; *Maricopa County v. Valley National Bank*, 318 U.S. 357,

360; *Helvering v. Griffiths*, 318 U.S. 371, 372; *Ecker v. Western Pacific R. Co.*, 318 U.S. 448, 452; *Emil v. Hanley*, 318 U.S. 515, 517).

3. Finally, when Sec. 502(j) is construed as purely a labeling provision the violation of which is to be determined accordingly, the record is devoid of proof to support a finding that Marmola is misbranded thereunder. As has been pointed out (*supra*, pp. 3-5), the proof is all the other way—even taking into consideration the testimony of the Government's witnesses alone. In other words, the Marmola *labeling*, in recommending an average daily dosage of 2 grains of desiccated thyroid for people with obesity caused by hypothyroidism who are otherwise normal and healthy (R. 8), is in accordance with recognized medical practice. The same thing is true of the directions in the Marmola labeling to stop taking it if any unpleasant effects are experienced until they disappear, and then resume in one-half the former dosage (R. 9).

While this Court will not review the concurrent findings of fact of a trial court and a circuit court of appeals where there is evidence in the record to support the same, it has indicated the propriety of its doing so on more than one occasion where, as in the instant case, there is no evidence in the record to support such concurrent findings and where the lower courts have failed to apply correct legal principles to the undisputed evidence (*Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 36; *General Talking Pictures Corp. v. Western Electric Corp.*, 304 U.S. 175, 178; *United States v. Appalachian Power Co.*, 311 U.S. 377, 403-4; *Seago, Administratrix v. New York Central R. Co.*, 315 U.S. 781; *Williams Mfg. Co. v. United Shoe Machinery Co.*, 316 U.S. 364, 365). Therefore, it is submitted that the foregoing is another sound reason for granting this petition.

Wherefore your petitioner prays that a Writ of Certiorari issue under the seal of this Court to the end that

this cause may be reviewed and determined by this Court, as provided for by the statutes of the United States in such case made and provided; that the judgment entered in the Circuit Court of Appeals for the Seventh Circuit be reversed by this Court, and for such further relief as to this Court may seem proper.

RALADAM COMPANY, *Petitioner,*

BY ROCKWELL T. GUST, AND
DAVID A. HOWELL,
Counsel for Petitioner.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1944

No.

RALADAM COMPANY, as Claimant of 62 Packages, more or less, of Marmola Prescription Tablets,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Respondent.

BRIEF IN SUPPORT OF THE FOREGOING PETITION FOR A WRIT OF CERTIORARI

OPINIONS OF THE COURTS BELOW

The opinion of the trial Court herein (R. 1298-1315) is reported in 48 F. Supp. 878; and the opinion of the Circuit Court of Appeals for the Seventh Circuit, affirming the same (R. 1353-9), is reported in 142 F. (2nd) 107. The pertinent parts of these opinions are discussed in the foregoing petition (*supra*, pp. 6-7, 10).

JURISDICTION

A statement of the grounds on which the jurisdiction of this Court to grant the foregoing petition is invoked and a statement of the reasons for granting the same are set forth therein (*supra*, pp. 12, 14-18). To avoid repetition, they are incorporated in this brief by reference.

STATEMENT OF THE CASE

A statement of the case is set forth in the foregoing petition (*supra*, pp. 1-11). Likewise, to avoid repetition, it is incorporated in this brief by reference.

SPECIFICATION OF ERRORS

The Circuit Court of Appeals for the Seventh Circuit erred, in affirming the decision of the trial Court herein, as follows:

I. In holding—contrary to the applicable decision of this Court in *McDermott v. Wisconsin*, 228 U. S. 115, 133—that the test of misbranding under Sec. 502(j) is whether there are any potential dangers *inherent* in *self-medication* with *effective* dosages of a drug, instead of holding that "the *label* is the *means* of *vindication* and the *basis* of *punishment*" in deciding this question; or, in other words, in failing to hold that Sec. 502(j) is purely a *labeling* provision the violation of which is to be determined accordingly.

II. In holding that Sec. 502(j) is subject to a construction which will prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for self-medica-

tion, because of the potential dangers *inherent* therein, and, at the same time, permit their continued labeling for use on a doctor's prescription—*despite* the wording of the other *misbranding* provisions of the statute in *pari materia* with Sec. 502(j), and its legislative history.

III. In failing to hold that the construction which it and the trial Court have placed on Sec. 502(j) casts grave doubt upon its constitutionality.

IV. In failing to hold that the record herein does not contain evidence which—as a matter of law—will support a finding that Marmola is misbranded under Sec. 502(j) when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly.

SUMMARY OF ARGUMENT

I. This Court held in *McDermott v. Wisconsin*, 228 U. S. 115, 130, 131, 132-3, that "the *label* is the *means* of *vindication* and the *basis* of *punishment*," in determining whether a drug is misbranded under a *labeling* provision —like Sec. 502(j); and that "this is the *only practical* or *sensible* construction" of such a provision. Consequently, the respective decisions of the lower Courts herein—holding, in effect, that a drug is misbranded under Sec. 502(j) regardless of the propriety of its labeling, if there are any potential dangers *inherent* in its use for self-medication—is in conflict with the decision of this Court in *McDermott v. Wisconsin, supra;* and this alone should furnish a sufficient reason for granting the foregoing petition for a writ of certiorari.

Furthermore, the conclusion reached by this Court in the *McDermott* case *is* "the *only practical* or *sensible* construction" of a *misbranding* provision—like Sec. 502(j). This is so for two outstanding reasons, among others, *viz.*, it is a cardinal principle of statutory construction, often enunciated and applied by this Court, that a statute

must be construed according to the *natural import* of its language, in order to carry out the legislative intent disclosed thereby, with the result that a *misbranding* provision—like Sec. 502(j)—must be construed as purely a *labeling* provision the violation of which is to be determined accordingly, because the *very term* "misbranded" connotes "*mislabeled.*" and, therefore, can define *only* a *labeling* offense; and it is an equally well-settled principle of statutory construction that a statute should be given a *sensible* construction which will avoid *absurd* results—such as making it impossible to label any useful drug known to *materia medica* for *self-medication* in *effective* dosages, without rendering it misbranded under Sec. 502(j), *per se*.

II. The wording of the other misbranding provisions of the statute in *pari materia* with Sec. 502(j), and its legislative history make it crystal clear that Congress did not intend Sec. 502(j) to be construed in such a manner as to prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for self-medication, because of the potential dangers *inherent* therein. Instead, the misbranding provisions of the statute—like Sec. 502(j)—are designed *merely* to make self-medication safer and more effective by requiring *adequate* and *proper labeling* of all drugs put on the market for such purposes. Hence, the contrary construction placed on Sec. 502(j) by the lower Courts herein is manifestly unsound and must be rejected; and it is submitted that the need for a proper settlement of this important question of federal law by this Court, at the earliest possible moment, should impel the granting of the foregoing petition for a writ of certiorari.

III. An additional reason for granting the foregoing petition for a writ of certiorari is that the construction placed on Sec. 502(j) by the lower Courts herein casts grave doubt upon its constitutionality, as being (1) an improper interference by Congress in a matter of purely

local concern; (2) an unwarranted attempt to prohibit the right of individual citizens of this country to medicate themselves with effective dosages of useful drugs—like desiccated thyroid—without any showing of harm to the public, in general, as a result of their so doing; and (3) a provision the violation of which entails severe penalties and forfeitures without furnishing any fair or ascertainable standard for gauging compliance therewith in advance of prosecution and punishment.

IV. Finally, the foregoing petition for a writ of certiorari should be granted because the record in this case does not contain evidence which—as matter of law—will support a finding that Marmola is misbranded under Sec. 502(j), when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly. All that the Government has proved—or really sought to prove—in this case is that there are certain potential dangers *inherent* in self-medication with desiccated thyroid in the Marmola dosage; and such proof is immaterial on the question of whether Marmola is *misbranded, viz.*, mislabeled, under Sec. 502(j).

ARGUMENT

I

In view of the applicable decision of this Court in *McDermott v. Wisconsin*, 228 U.S. 115, Sec. 502(j) is purely a *labeling* provision the violation of which is to be determined accordingly, with the result that "the *label* is the *means* of *vindication* and the *basis* of *punishment*" in deciding whether a drug is misbranded thereunder; and, hence, a decision that a properly labeled drug is misbranded under Sec. 502(j) merely because of the potential dangers *inherent* in self-medication with *effective* dosages thereof is in conflict with this Court's decision in *McDermott v. Wisconsin, supra.*

As has been more fully pointed out in the foregoing petition for a writ of certiorari (*supra*, pp. 14-15), this Court held in *McDermott v. Wisconsin*, 228 U. S. 115, 130, 131, 132-3, that, under "the only practical and sensible construction" of a *misbranding* provision—like Sec. 502(j)—"the *label* is the *means* of *vindication* and the *basis* of *punishment*" in deciding whether a drug is misbranded thereunder. Hence, the decision of the Circuit Court of Appeals for the Seventh Circuit, affirming the decision of the trial Court herein, is clearly in conflict with the applicable decision of this Court in *McDermott v. Wisconsin, supra*, because it holds, in effect, that a drug is misbranded under Sec. 502(j)—regardless of the propriety of its labeling—if there are any potential dangers *inherent* in *self-medication* with *effective* dosages thereof.

Furthermore, the conclusion reached by this Court regarding the proper construction of a *misbranding* provision—like Sec. 502(j)—is sound and in accordance with well-settled principles of statutory construction as will be more fully hereinafter pointed out.

A. A statute should be construed according to the natural import of its language, in order to carry out the legislative intent disclosed thereby.

The authorities are unanimous on the necessity of construing a statute according to the natural import of its language. In the case of *Lake County v. Rollins*, 130 U.S. 662, 670-1, this Court lucidly set forth the principle under discussion as follows:

> "To get at the thought or meaning expressed in a statute, a contract or a constitution, the first resort, in all cases, is to *the natural signification of the words*, in the order of grammatical arrangement in which the framers of the instrument have placed them. If the words convey a definite meaning which involves no absurdity, nor any contradiction of other parts of the instrument, then that meaning, apparent on the face of the instrument, must be accepted, and neither the courts nor the legislature have the right to add to it or take from it." (Italics ours)

More recent cases affirming and applying the foregoing principle are:

> *Thompson v. United States*, 246 U. S. 547,551; and
> *Magnano v. Hamilton*, 292 U. S. 40, 46-7.

The *Magnano* case is particularly apt because it was held that the statute under consideration therein was "plainly a taxing act" because of the language in which it was phrased.

1. Sec. 502(j) is a *misbranding* provision which speaks *solely* in terms of "labeling" and makes purely "labeling" requirements, with the result that it is to be construed and its violation determined accordingly.

Applying the elementary principle of statutory construction set forth in *Lake County v. Rollins*, 130 U. S. 662, 670-1, and the other cases immediately hereinabove discussed, it is clear that Sec. 502(j) is purely a *labeling* provision the violation of which is to be determined accordingly. This is so because Sec. 502(j) reads as follows:

> "A drug or device shall be deemed to be *misbranded*—
>
> "If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the *labeling* thereof." (Italics ours)

To *paraphrase* the ruling of this Court in *Magnano v. Hamilton*, 292 U. S. 40, 46-7:

> "Sec. 502(j) is in form plainly a *labeling* provision, with nothing in its terms to suggest that it was intended to be anything else."

2. The true test of compliance, or non-compliance, with a *misbranding* provision is—of necessity—the *propriety* of the *labeling* of a drug, *and that alone;* with the result that a drug is not "dangerous to health" within the meaning of Sec. 502(j) *unless* it is *made so* by improper labeling.

When it is appreciated that Sec. 502(j) speaks *solely* in terms of "labeling" and is, therefore, purely a *labeling* provision, the proposition that the *propriety* of the label-

ing of a drug furnishes the sole criterion of whether it is misbranded thereunder, would appear to follow—*a fortiori*. Accordingly, in *United States v.* 36 *Bottles of Gin* (C.C.A., 3rd), 210 Fed. 271, 272, the Circuit Court of Appeals for the Third Circuit ruled that the question of whether an article was *misbranded* under the Pure Food and Drug Act of 1906 depended *solely* on its *labeling*, as follows:

> "* * * This the label, *and the label alone*, must determine. * * *" (Italics ours)

As a matter of fact, if one stops to consider the ordinary and accepted meaning of the term "misbranded," it is apparent that Sec. 502(j) is directed solely against *mislabeling*, with the result that its violation is to be determined accordingly. This is so for the obvious reason that the very term "misbranded" means "mislabeled," and, therefore, can define *only* a *labeling* offense.

3. Consequently, any so-called "potential" dangers which may be "inherent" in self-medication with a *properly labeled* drug *after* it has been shipped in interstate commerce, are *immaterial* on the issue of whether it is *misbranded* for shipment under a *labeling* provision—like Sec. 502(j).

To recapitulate: this Court said, in *McDermott v. Wisconsin*, 128 U. S. 115, 133: "The *label* is the *means* of *vindication* or *the basis of punishment* in determining the character of the *interstate shipment* dealt with by Congress"; and, as the Circuit Court of Appeals for the Third Circuit put it in *United States v.* 36 *Bottles of Gin* (C.C.A., 3rd), 210 Fed. 271, 272, the issue of misbranding is one which "the label, *and the label alone*, must determine."

This being so, it is clear that any *dangers* which may be "inherent" in the *use*, or misuse, of a *properly labeled* drug for self-medication, following its interstate ship-

ment—which dangers concededly cannot be eliminated by any form of labeling—are wholly immaterial on the issue of whether it was misbranded *at the time* of shipment, *viz., mislabeled,* for shipment in interstate commerce.

In other words, it is difficult—if not impossible—to perceive how a drug that is *properly labeled* and, therefore, validly *branded* under the statute for shipment in interstate commerce, can thereafter suddenly become misbranded, without any change in its labeling, merely because of the possibility that some untoward consequences may arise from its use in violation of the directions, instructions, and limitations upon its use set forth in the labeling thereof. An explanation of how this transformation can take place without any visible change in the labeling—if forthcoming and comprehendable—will be most enlightening, to say the least.

B. Sec. 502(j) should be given a sensible construction which will avoid absurd results.

It is an equally well settled principle of statutory construction that a statute should be construed in a *sensible* manner, in the light of its language and purpose, so that *absurd results* may be avoided. The principle under discussion is well stated by this Court in the recent case of *Haggar Co. v. Helvering,* 308 U. S. 389, 394, as follows:

> "All statutes must be construed in the light of their purpose. A literal reading of them *which would lead to absurd results is to be avoided* when they can be given a reasonable application consistent with their words and with the legislative purpose. * * *" (Italics ours)

Earlier decisions of this Court to the same effect are the following;

> *United States v. Katz,* 271 U. S. 354, 357; and *Armstrong Co. v. Nu-Enamel Corp.,* 305 U. S. 315, 332-3.

1. If Sec. 502(j) is construed to require the recommendation of a dosage which can be taken *with impunity* in violation of the instructions for and limitations upon its use set forth in the labeling thereof it cannot be complied with because there is no effective dosage of any efficacious drug known to *materia medica*, which can be taken with safety under such conditions.

The trial Court held expressly (R. 1313)—and the Circuit Court of Appeals for the Seventh Circuit, in affirming the trial Court's decision, held, in effect (R. 1358)—that a drug must be considered "dangerous to health" within the meaning of Sec. 502(j) unless it can be taken in the recommended dosage with *impunity* "by the strong, the *weak*, the old, the *young*, the well, and the *sick*," indiscriminately, *viz.*, in willful or mistaken violation of the directions, instructions and limitations upon its use set forth in the labeling thereof. One of the basic troubles with any such construction of Sec. 502(j) is that it would lead to the absurd result of making virtually all drugs known to *materia medica* "dangerous to health" thereunder, *per se*.

This was forcefully pointed out by the Circuit Court of Appeals for the Sixth Circuit in *Raladam Co. v. Federal Trade Comm.*, 42 F. (2nd) 430, 433 (affirmed by the Supreme Court in 283 U. S. 643), as follows:

> "* * * Much is said in the testimony and the proofs about the toxic or poisonous quality of thyroid extract. There is no reason to doubt that it could be given in such quantity, or in the presence of *such conditions of bodily disease*, that the effect would be very deleterious, whether 'toxic' or not; but it is *equally clear*, and is admitted by the Commission's counsel, that there is *no drug* or *active agent* in the *entire bounds* of *materia medica*, which is not *by the same definition poisonous*." (Italics ours)

Dr. Klumpp, in speaking for the Food and Drug Administration, in charge of administering the statute under consideration, made it clear that it takes the same view of the matter, when he said (C.C.H. Food Drug Cosmetic Law Service, par. 10,216, p. 10,318):

> "But when shall we consider a drug safe? On first impression it might appear that *safety* can be considered *an isolated attribute* of a drug, *but this is not true*, since *every potent drug* carries with it *certain potentialities* for harm." (Italics ours)

In *Coca Cola Co. v. Koke Co.*, 254 U. S. 143, 145, Mr. Justice Holmes, speaking for this Court, put the matter aptly and succinctly, by saying:

> "* * * a drug * * * may be described as a deadly poison or as a valuable item of the pharmacopoeia according to the rhetorical purposes in view."

2. If, on the other hand, Sec. 502(j) is construed to require the recommendation of a dosage which can be taken with safety *according to* the directions, instructions and limitations on its use set forth in the labeling thereof, the requirement is reasonable and capable of fulfillment.

While it is impossible to recommend a dosage of a drug which will be *effective* in the treatment of *certain conditions* and, at the same time, *harmless* in the face of *all other conditions* which contra-indicate its use, no such difficulty is encountered in the requirement of recommending a safe dosage for the treatment of a *particular* condition, accompanied by warnings not to use it in the presence of other conditions which contra-indicate its use.

Such a requirement is *reasonable* and *capable of fulfillment*. It makes the *label* of the drug the *actual* test of

compliance, or *non-compliance*, with the statute. It carries out the purpose of the statute to make *self-medication safer* and *more effective* by requiring *adequate* and *proper labeling*, instead of accomplishing the absurd result of abolishing self-medication to all intents and purposes by making it impossible to label any *useful* drug and in *effective* dosages for such purpose.

Last, but not least, it avoids the vice of destroying a large and valuable industry with a useful function to perform, unless it can be seriously contended that Congress desired to give the medical profession a monopoly over practically all medication, without the usual concomitant safeguard, in such fostered monopolies, of governmental regulation of rates. Regardless of the view some may hold concerning the advisability of giving the medical profession such a monopoly, it will become increasingly apparent in the discussion which follows that such a view is not shared by Congress; and when all is said and done, Congress is the final arbiter in such matters.

In view of the foregoing, the ruling of this Court in *McDermott v. Wisconsin*, 228 U. S. 115, 133, that "the *label* is the *means* of *vindication* and the *basis* of *punishment*" in determining whether a drug is misbranded under a labeling provision—like Sec. 502(j)—is not only *sound*, but particularly *applicable* in the case at bar; and the decision of the Circuit Court of Appeals for the Seventh Circuit holding Marmola *misbranded* under Sec. 502(j)—regardless of the propriety of its labeling—because of the potential dangers *inherent* in self-medication with the Marmola dosage of desiccated thyroid—is clearly in conflict with the decision of this Court in *McDermott v. Wisconsin*, *supra*. Therefore, it is submitted that the foregoing petition for a writ of certiorari is well grounded and should be granted by this Court.

II

In view of the wording of the other misbranding provisions of the statute in *pari materia* with Sec. 502(j), and its legislative history, Sec. 502(j) *is not* subject to a construction which will prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for *self-medication,* because of the potential dangers *inherent* therein, and, at the same time, permit their continued labeling for use on a doctor's prescription; and this is an important question of federal law which has not been, but should be, settled by this Court.

As has been pointed out in the foregoing petition (*supra*, pp. 6-7, 10-11), the Circuit Court of Appeals for the Seventh Circuit, in affirming the decision of the trial Court herein, placed a construction on Sec. 502(j) *which* will prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for *self-medication,* because of the potential dangers *inherent* therein, and, at the same time, permit their continued labeling for use on a doctor's prescription. In so construing Sec. 502(j), the Circuit Court of Appeals for the Seventh Circuit has decided an important question of federal law which has not been, but should be, settled by this Court; and this is particularly true in view of the fact that unsound character of such a construction of Sec. 502(j) becomes readily apparent upon an examination of the other misbranding provisions of the statute in *pari materia* with Sec. 502(j), and its legislative history—as will be fully hereinafter demonstrated.

A. The scope and proper application of Sec. 502(j) should be determined in the light of the other misbranding provisions of the statute, so that each of them will have some useful function to perform and none of them will be rendered nugatory or inconsistent therewith.

There is probably no principle of statutory construction which is better settled than that the provisions of a statute should be so construed as to be consistent with one another, and so that each of them will have some useful function to perform. The principle under discussion is stated by this Court in *Ex Parte Public National Bank*, 278 U. S. 101, 104, as follows:

> "No rule of statutory construction has been more definitely stated or more often repeated than the cardinal rule that 'significance and effect shall, if possible, be accorded to every word. As early as in Bacon's Abridgment, sect. 2, it was said that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." ' Market Co. v. Hoffman, 101 U. S. 112, 115. * * *"

See also *Hellmich v. Hellman*, 276 U. S. 233, 236-7.

1. If Sec. 502(j) is construed to prevent the labeling of desiccated thyroid for self-medication in *effective* dosages, Sec. 502(e) of the statute will be rendered nugatory—*pro tanto*—because Sec. 503(b) exempts drugs dispensed on a doctor's prescription from Sec. 502(e); with the result that unless desiccated thyroid and the other drugs named therein can be labeled for self-medication in *effective* dosages, Sec. 502(e) has no useful purpose to serve.

A conclusive and unanswerable reason why Sec. 502(j) cannot be construed to prevent the labeling of desiccated thyroid for self-medication in effective dosages is that such a construction would render Sec. 502(e) of the statute nugatory—*pro tanto*—contrary to the principle of statutory construction immediately hereinabove discussed. This is so, because Sec. 503(b) of the statute exempts drugs dispensed on a doctor's prescription from certain of the misbranding provisions of the statute, *including Sec.* 502(e), thereby limiting the application of Sec. 502(e) to the labeling of drugs for self-medication, as follows:

> Sec. 503(b). "A drug dispensed on a written prescription signed by a physician * * * shall * * * be exempt from the requirement of Sec. 502(b) *and* (*e*) * * *." (Italics ours)

Sec. 502(e) of the statute, from which drugs dispensed on a doctor's prescription are exempt as aforesaid, *expressly* applies to the *labeling* of "active," *viz.*, *effective* dosages of *desiccated thyroid*, as follows:

> Sec. 502(e). "A drug shall be deemed to be misbranded—
>
> "If it is a drug that is not designated solely by a name recognized in an official compendium unless its *label* bears (1) the common or usual name of

> the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each *active* ingredient, including the quantity, kind and proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any • • • *thyroid*, or any derivative or preparation of any such substances, contained therein." (Italics ours)

Hence, it follows that unless *effective* dosages of desiccated thyroid can be labeled and used for *self-medication*, the labeling requirements of Sec. 502(e) immediately hereinabove set forth have no purpose to serve so far as desiccated thyroid is concerned, and this provision of the statute is rendered nugatory—*pro tanto*.

Stated differently—the statute by making express provision for the labeling of "active," *viz.*, *effective* dosages of desiccated thyroid for self-medication, has recognized that it may be sold in such dosages for such purpose, provided—*and provided only*—that the *labeling* requirements of the statute are complied with. This being so, it is clear that a construction of the statute which would prevent the labeling of *effective* dosages of drug products containing desiccated thyroid, such as Marmola, for self-medication—not because they are mislabeled, but merely because of the so-called "potential" dangers which may be "inherent" in their use for such purpose—is utterly fallacious.

2. If Sec. 502(j) is construed to prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for self-medication because of the so-called "potential" dangers "inherent" therein, the requirement of Sec. 502(f) that the labeling of such dosages of such drugs for self-medication shall contain warnings of such dangers becomes mere surplusage.

Sec. 502(f) requires that the labeling of *effective* dosages of a drug for self-medication shall contain

> "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health."

Obviously, this provision has a purpose to serve *only* in the event that, except for the required "warnings," such dosages of a drug might be used for self-medication in the presence of such "pathological conditions or by children." Conversely, if *effective* dosages of drugs are unavailable for self-medication, because of such dangers, no such possibility exists, with the result that the requirement of Sec. 502(f) concerning such "warnings" would be mere surplusage because of the lack of any opportunity for the warnings to be heeded.

To take a homely example, a statutory requirement that a railroad company erect warning signals and other safety devices at grade crossings would be rendered mere surplusage by another provision of the same statute prohibiting the maintenance of grade crossings. By the same token, to construe Sec. 502(j) as preventing self-medication with *effective* dosages of useful drugs—like desiccated thyroid—would render useless the requirements of Sec. 502(f) for the labeling of such dosages of such drugs with warnings of the so-called "potential" dangers "inherent" in self-medication therewith.

3. If, on the other hand, Sec. 502(j) is construed as purely a *labeling* provision designed to make self-medication *safer* by eliminating dangers *created by* improper labeling, Secs. 502(e) and 502(f) will be consistent therewith and have a useful function to perform.

While construing Sec. 502(j) to prevent the labeling and consumption of useful drugs—like desiccated thyroid —for self-medication because of the so-called "potential" dangers "inherent" therein, will render Secs. 502(e) and 502(f) nugatory or mere surplusage as hereinabove pointed out; no such difficulty is encountered if Sec. 502(j) is construed as purely a *labeling* provision designed to require the recommendation of a dosage which is safe for the persons *for whom* the drug is *prescribed* in its labeling.

In other words, when Sec. 502(j) is construed as purely a *labeling* provision the violation of which is to be determined accordingly, it not only will be possible to label desiccated thyroid and other useful drugs for self-medication in compliance with its provisions, but the provisions of Secs. 502(e) and 502(f) become complimentary thereto—instead of being inconsistent therewith—and have a useful function to perform. This being so, such a construction of Sec. 502(j) is the one that must be adopted under the decisions of this Court hereinabove discussed (*supra*, p. 33).

B. Sec. 502(j) should be construed with reference to the principle that an exemption in a statute amounts to an affirmation of its application to all other like matters not exempted, and excludes all other exemptions.

The principle that an exemption in a statute amounts to an affirmation of its application to all other situations not exempted, and excludes all other exemptions, was adopted and applied by this Court at an early day in *Bend v. Hoyt*, 13 Peters 263, 271-2, as follows:

> "* * * the case before us does not turn upon the interpretation of the second clause *standing alone*, but it is materially affected by the fifteenth clause of the same section of the act, which prescribes a rate of duty on manufactures of silk, in the following words: 'On all manufacturers of silk or of which silk shall be a component part, coming from beyond the Cape of Good Hope, ten per centum ad valorem, and on all other manufactures of silk, or of which silk is a component part, five per centum ad valorem, *except sewing silk*, which shall be forty per centum ad valorem.' Now, this language in its positive import, includes all manufactures of silk except sewing silk; and the very exception of sewing silk lends additional force to the conclusion, that no other manufactures of silk were intended to be excepted from the operation of the clause, upon the well known maxim, that *an exception in a statute amounts to an affirmation of the application of its provisions to all other cases not excepted.* * * *" (Italics ours)

See also *Equitable Life Society v. Clements*, 140 U. S. 226, 233; and *Moore Ice Cream Co. v. Rose*, 289 U. S. 373, 377, for more recent decisions of this Court applying the principle under discussion.

1. Sec. 503(b) exempts drugs dispensed on a doctor's prescription from some of the misbranding provisions of the statute *but not from Sec. 502(j)*, with the result that if Sec. 502(j) is construed to prevent the labeling of *effective* dosages of desiccated thyroid for self-medication, it must also be construed to prevent their labeling for use on a doctor's prescription.

As has been seen (*supra*, p. 34), Sec. 503(b) of the statute exempts drugs dispensed on a doctor's prescription from certain of the misbranding provisions of the statute. However, it does not exempt drugs so dispensed from Sec. 502(j). Hence, under the authorities immediately hereinabove discussed, Sec. 502(j) must be construed to apply with equal force to a drug regardless of whether it is labeled for self-medication or for use on a doctor's prescription.

This being so, if *effective* dosages of useful drugs—like desiccated thyroid—cannot be labeled for self-medication without offending Sec. 502(j), they cannot be labeled for use on a doctor's prescription thereunder. Conversely, if such dosages of such drugs can be labeled for use on a doctor's prescription under Sec. 502(j), they can also be labeled for self-medication thereunder.

Therefore, it follows that any effective dosage of any drug, which can be labeled for use on a doctor's prescription, can also be labeled for self-medication; and, as has been seen, the Marmola dosage of desiccated thyroid falls in this category, because it is the "generally established" (R. 115) average dosage of desiccated thyroid prescribed by the medical profession (R. 55, 87, 115, 248, 544, 608, 639, 647, 686, 710-11, 892).

C. If any doubt remains concerning the proper construction of Sec. 502(j), it should be resolved in favor of its purpose and intent as disclosed by its legislative history.

The function to be served and weight to be accorded the legislative history of a statute in arriving at its proper construction is stated in *McCaughn v. Hershey Chocolate Co.*, 283 U.S. 488, 492, as follows:

> "Possible doubts as to the proper construction of the language used should be resolved in the light of its administrative and legislative history. * * *"

See also *Gay v. Ruff*, 292 U.S. 25, 31; and *Fed. Security Admin. v. Quaker Oats Co.*, 318 U.S. 218, 230. In the case last mentioned this Court placed considerable reliance on the legislative history of other provisions of the statute under consideration in this case, in arriving at its decision.

1. The legislative history of the statute discloses that Sec. 502(j) is purely a labeling provision designed to make self-medication safer by requiring adequate and proper labeling, and that it is not designed to prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for self-medication, merely because of the "potential" dangers "inherent" therein.

Finally, if anything more is needed to demonstrate that Sec. 502(j) is purely a *labeling* provision designed to make self-medication safer by requiring adequate and proper labeling, and that it is not designed to prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for self-medication, merely because of

the "potential" dangers "inherent" therein, it is furnished by the legislative history of the statute. This, fortunately, is available in convenient form for the use of this Court and counsel in the "*Federal Food, Drug and Cosmetic Act*—a Statement of Its Legislative History"—by Charles Wesley Dunn (1st Ed., published 1938).

While there is a tremendous amount of material available in the legislative history, which demonstrates conclusively that Congress had no intention of passing a statute which might be construed to deprive individuals of what Congress regarded as their right of self-medication with effective dosages of useful drugs—like desiccated thyroid—so much of this material is merely cumulative on the point that a few excerpts therefrom should be sufficient to demonstrate the same. The figures in parentheses, appearing in the following discussion, refer to the pertinent pages of Mr. Dunn's Legislative History of the Act.

Before delving into this legislative history in any detailed manner, it is interesting to note that more than six different bills were introduced in Congress during seven different sessions (vii-ix), covering a period exceeding five years, five of which bills were allowed to die before Congress could be induced to pass the present statute. As appears from the legislative history, it did so then only with considerable reluctance, because of the fear that it might possibly be perverted into a ban of self-medication to some extent. In addition, it is worthy of note that the first bill introduced in Congress was drafted in the Department of Agriculture (24) and that Mr. Walter G. Campbell, both then and until very recently Chief of the Food and Drug Administration, a subdivision of the Department of Agriculture, was one of the principal sponsors of the legislation. Consequently, his statements to Congress, regarding the purpose and scope of the legislation are entitled to more than ordinary weight.

The first bill was introduced in the Senate on June 12, 1933, and was known as Senate 1944 (37). Section 4 of that Act provided:

> "Sec. 4. A drug shall be deemed to be adulterated—
>
> "(a) If it *is* or *may be* dangerous to health under the conditions of use prescribed in the labeling thereof." (38-9) (Italics ours)

Hearings were had on Senate 1944 before a subcommittee on December 7 and 8, 1933 (1048). During the course of these hearings, Mr. Campbell made the following pertinent statement:

> "*There is no issue,* as I have told you previously, from the standpoint of the enforcement of the Food and Drugs Act *about self-medication.*
>
> "This bill does not contemplate its prevention *at all.* If it did *a single short section* in the measure could have been drawn up *to that effect.*" (1083) (Italics ours)

It is submitted that the most careful examination of the statute as finally passed fails to reveal any "single short section" which expresses an intention to prevent self-medication to any extent, or even a long one for that matter. Nevertheless, the effect of the decision of the Circuit Court of Appeals for the Seventh Circuit, affirming the trial Court's decision herein, is to convert the statute from one that did not contemplate the prevention of self-medication "*at all*" into one that will do away with it *entirely,* if it is followed to its logical conclusion, as it must be, if it is sound—as has been pointed out in the foregoing petition (*supra*, pp. 10-11).

Senate 1944 died in the Senate Committee on Commerce, where it was superseded by a second bill known as Senate 2000 (50). This second bill also died in Committee without any hearings being held on the same, and

was superseded by a third bill known as *Senate* 2800 (67). Hearings were held on this Bill before the Senate Committee on Commerce from February 27 through March 3, 1934 (87). At one of these hearings Mr. Campbell again took occasion to reassure the Senate Committee that the proposed legislation was not designed to interfere to any extent with the right of self-medication, as follows:

> "And let me stop just at this point to comment upon the criticism so extensively voiced by the patent-medicine interest that *the purpose of this bill is to stop self-medication.* This paragraph (a) of section 9* would certainly be unnecessary if it were not contemplated that *self-medication will continue in the future as it has in the past.* Physicians do not need such information; nor would they need but little of the information required by the succeeding paragraphs of this section. All of the provisions dealing with drugs, aside from those recognized in the official compendia, are directed towards safeguarding the consumer *who is attempting to administer to himself.* If this measure passes, self-medication will become infinitely more safe than it has ever been in the past" (1195). (Italics ours)

On the strength of assurances such as these Senator Copeland, Chairman of the Senate Committee, which had held the hearings on Senate 2800, as aforesaid, made a statement "formulated with a view to describing the bill and *its purposes*" (87) and submitted a Committee Report (110) to the Senate regarding the purpose and scope of the proposed bill. In his *statement* Senator Copeland denied emphatically that the bill was intended to prevent self-medication with effective dosages of useful drugs—like desiccated thyroid—as follows:

> "There is no more common or mistaken *criticism* of this bill than *that it denies the right of*

*Section 9 was a *misbranding* section of the bill which Mr. Campbell was then discussing.

> *self-medication,* or, as the objector usually put it, 'You can't take an aspirin tablet without a doctor's prescription.' *Nothing could be further from the truth.* The proposed law simply *contributes to* the safety of self-medication by preventing medicines from being sold as 'cures' unless they really are cures. It requires that drugs which have only palliative effect shall say as much on the label.
>
> * * * * *
>
> "As regards drugs, the bill provides that particularly potent drugs are to be declared. The label must carry a warning against habit-forming drugs and overdosage. We believe these provisions insure *adequate* public protection without imposing unreasonable hardships on anybody" (89-90, 91). (Italics ours)

The pertinent part of the Committee Report which was prefaced by the foregoing *statement* of Senator Copeland, reads as follows:

> "Section 4. Adulterated Drugs.
>
> "Section 4 defines adulterated drugs. Paragraph (a) defines as adulterated a drug which is dangerous to health under conditions of use prescribed in its labeling. There are *no useful drugs* which would be *banned from the market* under this provision since *labeling* with proper directions for use *would remove any worth-while drug* from this ban. * * *" (114-115). (Italics ours)

Another statement in the legislative history of the statute, which discloses that Congress did not intend to put an end to self-medication with effective dosages of useful drugs—like desiccated thyroid—despite its recognition of the so-called "potential" dangers which may be "inherent" therein, but merely intended to make self-medication safer by requiring adequate and proper labeling, appears in a further statement by Senator Copeland

to the Senate concerning the purpose and intent of the bill designated Senate 2800, as follows:

> "There are *many* very *useful* drugs which should be employed only with great care and discretion because in improper dosage or when administered to children or *when the patient is suffering from certain disease complications,* the effect of these drugs may be disastrous. S. 2800 provides *an effective safeguard against these dangers* which cannot be controlled under the present law. It requires that all drugs bear *explicit directions for use* and appropriate *warnings* against their consumption *by children* or *in certain disease conditions* where the use is contraindicated" (162). (Italics ours)

Substantially the same statement appears in the Senate Report (254) and House Report (484) on Senate 5, which is the bill that was finally enacted, as aforesaid.

After *Senate* 2800 had died on the Senate Calendar (188), the Food and Drug Administration made the following statement in its annual report (189) for the fiscal year 1934, by way of explanation of the failure of Congress to pass the proposed legislation:

> "A vast amount of *misinformation* to the effect that the bill if passed would result in destruction of legitimate industries, *interfere* with *the right* of *self-medication,* and deny manufacturers their constitutional rights, was disseminated not only among the industries but among the public." (190) (Italics ours)

On January 4, 1935, *Senate* 5 was introduced by Senator Copeland, and again referred to the Committee on Commerce (191). Hearings on this bill were held before the Committee on March 2, 8 and 9, 1935 (1213); and again Mr. Campbell appeared and reaffirmed his earlier

statements hereinabove discussed concerning the scope and intended purpose of the proposed bill, the pertinent part of which reads as follows:

> "Mr. Chairman. I spoke at length at both of the previous hearings. Most of what I said before, and then, if not everything that I said is applicable in substantial measure to a consideration of the present bill S. 5" (1222).

The Committee submitted its report to the Senate on March 26, 1935 (237), and on the strength of assurances such as Mr. Campbell's again commented on the purpose and scope of the "dangerous drug" provision of Senate 5, which provision is now Sec. 502(j) of the present statute, as follows:

> "Section 401(a) (1) defines a drug as adulterated if it is dangerous to health under the conditions of use prescribed in its labeling or advertising. There are *no useful drugs* which *would be banned* from the market under this provision, *since labeling with proper directions for use* would remove any worth-while drug from this ban. * * *
>
> "It will be noted that this provision in S. 5 differs from a similar provision in at least one of the bills considered by the last Congress, in that *the words 'or may be' have been deleted* before 'dangerous to health.' This is for the reason that there are certain drugs whoes employment is necessary in the treatment of some diseases which, none the less, *may in very exceptional cases prove harmful* to persons to whom they are administered. Their action in such circumstances is comparable to the allergic action of eggs and other common foods, which was discussed in connection with paragraph (a) of section 301. *It is not intended* that this provision *should ban the sale of useful drugs of this kind* when they are *appropriately labeled*" (250) (Italics ours)

At an earlier point in this brief (*supra*, pp. 34-35) it was demonstrated that *if* Sec. 502(j) is construed to prevent self-medication with desiccated thyroid, Sec. 502(e) would be made nugatory. If anything more is needed to demonstrate that the statute was not designed to make effective dosages of *desiccated thyroid* unavailable for self-medication, regardless of its effect on other drugs, it is furnished by the following statement in the Report made to the Senate on the *final* bill, concerning the purpose of Sec. 502(e):

> "Paragraph (e) of this section requires that drugs sold as other than pharmacopoeial or formulary preparations be labeled with their common or usual name, if they have such names, and if they are fabricated from two or more ingredients, the name of each *active* ingredient, including any alcohol. * * * the consumer of drugs certainly has the right to know something of the identity of the active ingredients, *particularly if he is undertaking to medicate himself* and is thus *acting the role of physician to himself.* In such circumstances he has as much right, as does the physician, to know the identity of the drugs he is administering" (253-4). (Italics ours)

Futhermore—and this should be conclusive on the subject—in the Report of the House Committee on the *final* bill, it was again stated:

> "The bill *is not intended to restrict* in any way *the availability of drugs for self-medication.* On the contrary, it is intended to make self-medication safer and more effective" (822). (Italics ours)

To summarize the legislative history of the statute, it discloses, *first*, that the present Act was obtained from Congress only after great travail and in the face of determined opposition because of the persistent fear on the part of many Senators and Congressmen that it might be utilized to deprive individuals of their right of self-

medication; *second,* that the statute would never have been passed except for the repeated assurances of sponsors of the legislation, like Mr. Campbell, to the effect that "There *is no issue* * * * *about self-medication.* This bill does not contemplate its prevention *at all*" (1083); and, *third,* that, even in the presence of such assurances, Congress exercised the greatest caution to revise the language of any provision of the statute which might otherwise be construed to interfere *"in any way"* with the right of self-medication.

In the face of such a legislative history, it is clear that the statute is not open to a construction that will limit the right of self-medication with *properly* labeled drugs—like Marmola—"in *any* way." Congress having taken every possible precaution to preserve such right inviolate, without any limitation *"at all,"* and sponsors of the legislation—like Mr. Campbell—having repeatedly assured Congress that this purpose had been accomplished in the bill as finally passed, the construction of the statute adopted by the lower Courts herein is obviously improper; and this is so no matter how limited an encroachment on the right of self-medication is intended thereby, or how beneficial from a public health standpoint some persons may believe such an encroachment to be. Congress being the final arbiter of such matters, its judgment must be accepted as conclusive; and no appeal therefrom to courts can be had.

In view of the foregoing, it is apparent that Sec. 502(j) is not open to a construction which will prevent the labeling of effective dosages of useful drugs—like desiccated thyroid—for self-medication, because of the potential dangers *inherent* therein, and, at the same time, permit their continued labeling for use on a doctor's prescription.

This is so—among other reasons—because both the wording of the statute and the legislative history reveal that Congress did not "intend to restrict *in any way* the

availability of drugs for self-medication"; but merely desired "to make self-medication safer and more effective" (*supra*, p. 47), by requiring that "active," *viz.*, effective, dosages of desiccated thyroid (*supra*, pp. 34-35, 47) and other useful drugs offered to the public for self-medication be adequately and properly labeled for such purpose (*supra*, pp. 43-46).

The wording of the statute and its legislative history also reveal that Congress had no intention of giving the medical profession a monopoly over dispensing useful drugs—like desiccated thyroid. Sec. 502(e) not only makes specific requirements which apply *solely* to the labeling of *desiccated thyroid*—and the other drugs mentioned therein—*for self-medication* (*supra*, pp. 34-35), but Sec. 502(j) applies with equal force to all drugs regardless of whether they are labeled for self-medication, or use on a doctor's prescription (*supra*, pp. 38-39).

Hence, it is clear that the Circuit Court of Appeals for the Seventh Circuit, in affirming the decision of the trial Court herein, has not only decided an important question of federal law which has not been, but should be, settled by this Court; but it has decided it contrary to well-settled principles of statutory construction and the express intention of Congress as disclosed by the legislative history of the statute. Under these circumstances, it is submitted that the foregoing petition for a writ of certiorari should be granted, in order that this Court may be given the opportunity to review and correct this erroneous decision which is of such vital importance to the public at large.

III

The construction placed on Sec. 502(j) by the decision of the Circuit Court of Appeals for the Seventh Circuit, affirming the decision of the trial Court herein, casts grave doubt upon its constitutionality; and this furnishes an additional reason for granting the foregoing petition for a writ of certiorari.

An additional reason for granting the foregoing petition for a writ of certiorari is that the decision of the Circuit Court of Appeals for the Seventh Circuit, affirming the decision of the trial Court herein, places a construction on Sec. 502(j) which casts grave doubt on its constitutionality as being (1) an improper interference by Congress in a matter of purely local concern; (2) an unwarranted attempt to prohibit the right of individual citizens of this country to medicate themselves with effective dosages of useful drugs—like desiccated thyroid—without any showing of harm to the public, in general, as a result of their so doing; and (3) a provision the violation of which entails severe penalties and forfeitures without furnishing any fair or ascertainable standard for gauging compliance therewith in advance of prosecution and punishment—all as more fully hereinafter pointed out.

A. If two constructions of Sec. 502(j) are possible, the one should be selected which will avoid doubt as to its constitutionality.

Few principles of statutory construction are better established or more frequently applied than that a statute should be construed, if possible, in such a manner as to avoid doubt concerning its constitutionality. The principle referred to is well stated in *United States v. Standard Brewery*, 251 U. S. 210, 220, as follows:

"Furthermore, we must remember in considering an act of Congress that a construction which *might* render it unconstitutional *is to be avoided.* * * * " (Italics ours)

For more recent decisions of this Court to the same effects, see *United States v. Shreveport Grain & Elevator Co.*, 287 U. S. 77, 81-2; and *N. W. Bell Telephone Co. v. Railway Comm.*, 297 U. S. 471, 480.

1. If Sec. 502(j) is construed as being designed to put an end to self-medication with effective dosages of useful drugs—like desiccated thyroid—within the various States, doubt will be cast upon its validity because it is questionable whether Congress has the power to legislate concerning such matters.

In *Linder v. United States*, 268 U. S. 5, 18, this Court, in reversing the conviction of a physician for an alleged violation of the Narcotic Act, made the following pertinent remarks:

"Obviously, direct control of medical practice in the States is beyond the power of the Federal Government. Incidental regulation of such practice by Congress through a taxing act *cannot extend to matters plainly inappropriate and unnecessary* to reasonable enforcement of a revenue measure. * * *" (Italics ours)

A later decision of this Court to the same effect is that of *Nigro v. United States*, 276 U. S. 332, 341, wherein it was held:

"In interpreting the Act, we must assume that it is a taxing measure, for otherwise it would be no law at all. If it is a mere act for the purpose of *regulating* and *restraining the purchase* of the

> opiate and other drugs, it is beyond the power of Congress and must be regarded as invalid. * * *" (Italics ours)

If any attempt to restrain the purchase and use of narcotics within the various States is deemed to be beyond the powers of Congress as this Court held in the decisions immediately hereinabove discussed, it is submitted that a similar attempt to put an end to self-medication with useful and relatively harmless drugs—like desiccated thyroid—within the various States would be so for the same reason. In any event—and this is all that is necessary for the purposes of arriving at a decision herein—there can be little question but that construing Sec. 502(j) in such a manner will cast doubt upon its constitutionality, with the result that it is a construction which should be avoided.

2. If Sec. 502(j) is construed as an attempt by Congress to deprive individuals of their right of self-medication with effective dosages of useful drugs—like desiccated thyroid—its validity will be open to serious question.

Even more serious doubts concerning the constitutionality of Sec. 502(j) will be raised by a construction thereof which deprives individuals of what has always been considered their inalienable right to self-medicate with useful drugs—like desiccated thyroid—in the absence of any public necessity for depriving them of such right. It is fundamental, under our Constitution, that private rights shall not be called upon to yield merely because a majority feel that the individual seeking their exercise should be deprived of the privilege *for his own good*. The right of the individual to regulate his private life and solve his private health problems as he sees fit—even though unwisely in the view of persons who consider

themselves more enlightened—so long as he does not encroach upon the rights of others, has always been considered one of our fundamental liberties guaranteed by the Constitution. Indeed, the thought has often been expressed that without such a guarantee the Constitution would never have been ratified or adopted.

It may be that the layman who doctors himself with any drug has a fool for a patient. Likewise, it may be that a person who attempts to cure his illness by resorting to Christian Science, chiropractics, osteopathy, homeopathy, physical culture, mineral baths, taking the sun cure, etc., is foolish and unenlightened. The man who eschews all drugs and all medical supervision in his search for health may be more or less wise than the one who makes a choice between self-medication with certain drugs and a "competent" physician. Nevertheless, who can gainsay that our Constitution has guaranteed to each of us the inalienable right to follow our own dictates in such matters—even in the face of our neighbors' disapprobation—provided only that we do not jeopardize our neighbors' health in so doing.

In the recent case of *W. Va. Bd. of Education v. Barnette*, 319 U. S. 624, 630, 638, 639-40, this Court reversed itself in order to safeguard individual liberties—far less valued, universally—against unnecessary encroachment by governmental authority. The pertinent parts of this Court's opinion, holding unconstitutional a requirement that teachers and school children salute the flag, read as follows:

> "The freedom asserted by these appellees *does not bring them into collision with rights asserted by any other individual.* It is such conflicts which most frequently require intervention of the State to determine where the rights of one end and those of another begin. But the refusal of these persons to participate in the ceremony *does not interfere with or deny rights of others to do so.* • • •
>
> • • • • •

"The very purpose of a Bill of Rights was to withdraw certain subjects from the vicissitudes of political controversy, *to place them beyond the reach of majorities and officials and to establish them as legal principles* to be applied by the courts. One's right to life, liberty, and property, to free speech, a free press, freedom of worship and assembly, and other fundamental rights *may not be submitted to vote; they depend on the outcome of no elections.*

"* * * They are susceptible of restriction *only* to prevent grave and *immediate danger* to interests which the state may lawfully protect. * * *

"Nor does our duty to apply the Bill of Rights to assertions of official authority depend upon our possession of marked competence in the field where the invasion of rights occurs. * * * We cannot, because of modest estimates of our competence in such specialties as public education, withhold the judgment that history authenticates as the function of this Court when liberty is infringed." (Italics ours)

See also *Jacobson v. Massachusetts,* 197 U.S. 11, wherein the constitutionality of a statute providing for the compulsory vaccination for smallpox was sustained *solely* because of the greater public necessity involved; and *Meyer v. Nebraska,* 262 U.S. 390, wherein a statute prohibiting the teaching of foreign languages to grade school pupils was invalidated because of the lack of such public necessity.

Looking at the situation under consideration in the instant case, it is perfectly clear that there is no public necessity for preventing an individual from medicating himself with useful drugs—like desiccated thyroid—if, as, and when he sees fit. Conversely, there is no public necessity for requiring the layman to pay unwilling tribute to the medical profession to obtain these drugs. His

failure to try to find a "competent" physician every time he wants to take some medicine "does not interfere with or deny rights of others to do so," nor does it cause "grave and immediate danger" to *others,* as this Court so aptly states the test of "public necessity" in the *Barnette* case, *supra.*

Therefore, it is submitted that, under the foregoing decisions of this Court, the right of self-medication with effective dosages of useful drugs—like desiccated thyroid —is one preserved by the Constitution; and any statute which attempts to infringe the same is of doubtful validity, to say the least. This being so, the construction of Sec. 502(j) which deprives the public of this right is one which must be avoided.

3. Unless Sec. 502(j) is construed as purely a labeling provision the violation of which is to be determined accordingly, doubt will be cast upon its constitutionality, because of its failure to furnish a reasonable standard of compliance therewith which is ascertainable in advance of prosecution.

Finally, a statute to be constitutional must provide a fair standard or reasonable test that will enable persons subject to its provisions to determine in advance of prosecution what they must do in order to comply therewith, instead of waiting to find out in criminal or forfeiture proceedings brought for the alleged violation thereof.

In *United States v. Cohen Grocery Co.,* 255 U.S. 81, 89, this Court, in holding the Lever Act unconstitutional, made the following pertinent remarks:

> "* * * It confines the subject-matter of the investigation which it authorizes to *no* element *essentially inhering in the transaction as to which it provides.* It leaves open, therefore, *the widest con-*

> *ceivable inquiry, the scope of which no one can foresee and the result of which no one can foreshadow or adequately guard against.* In fact, we see no reason to doubt the soundness of the observation of the court below, in its opinion, to the effect that, to attempt to enforce the section would be the exact equivalent of an effort to carry out a statute which in terms merely penalized and punished *all acts detrimental to the public interest when unjust and unreasonable* in the *estimation* of the court and jury." (Italics ours)

To the same effect see *Connally v. General Construction Co.*, 269 U.S. 385, 391-5, wherein this Court's decisions on the question are gathered together and rationalized.

Applying the ruling in the foregoing decisions to the instant case, no standard is or could be provided in the statute which would enable a manufacturer or distributor of a drug to anticipate and prevent a person from taking it *in disregard* of the directions, instructions and limitations upon its use in the labeling thereof. It is common knowledge that even drugs dispensed on a doctor's prescription are not infrequently taken *in violation of* his instructions or by persons *other than those* for whom he has prescribed them. Clearly, it can not be contended that any such test should be applied to effective dosages of useful drugs dispensed on a doctor's prescription; and, yet, as has been shown (*supra*, p. 39) Sec. 502(j) applies with equal force to all drugs whether they are to be used for self-medication or on a doctor's prescription.

The statute contains no list of "dangerous" drugs, nor any formula which will enable anyone to segregate them from the other drugs in *materia medica*, except that the lower Courts' definition of when a drug is "dangerous to health" within the meaning of Sec. 502(j) includes virtually all drugs known to *materia medica*—as has been pointed out in the foregoing petition (*supra*, pp. 6-7, 10-11).

Furthermore, under the construction placed on Sec. 502(j) by the lower Courts herein, the dangerous character of a drug in a given case would apparently depend on a highly variable factor entirely beyond the control of the manufacturer or distributor of the drug, namely, whether some prospective consumer might, in the future, disregard the directions, instructions, and warnings in the labeling, and get into difficulty as a result of so doing. Thus, the violation of the statute would depend on "no element essentially inhering in the transaction as to which it provides," and this was regarded as a fatal defect by this Court in *United States v. Cohen Grocery Co., supra.*

4. If, on the other hand, Sec. 502(j) is construed as purely a labeling provision the violation of which is to be determined accordingly, such a construction is not only sensible and consistent with its language but will avoid any doubt as to its constitutionality.

In *McDermott v. Wisconsin*, 228 U.S. 115, 131, hereinabove discussed in another connection (*supra*, pp. 24-28, 31) this Court made the following pertinent statement as to why *misbranding* provisions—like Sec. 502(j)—should be construed as purely *labeling* provisions the violation of which should be determined accordingly:

> "The *object* of the statute, is to prevent *the misuse of the facilities of interstate commerce in conveying to* and *placing before* the consumer misbranded and adulterated articles of medicine or food, * * * This is *the only practical or sensible construction of the act*, and, for the reasons we have stated, we think the requirements of the act *as so construed* clearly *within the powers* of Congress over the facilities of interstate commerce, and such has been the construction generally placed upon the act by the Federal courts." (Italics ours)

Thus, if Sec. 502(j) is construed as purely a *labeling* provision the violation of which is to be determined accordingly—as its wording and legislative history show it should be—such a construction is not only *sensible* and *consistent with its language*, but all of *the doubts regarding its constitutionality*, which would arise under the construction placed thereon by the lower Courts herein, are immediately dispelled. Sec. 502(j) then becomes a regulation of the *labeling* of drugs *for* shipment in interstate commerce, with the result that the *label* which the manufacturer or distributor of a drug places thereon furnishes the *sole* criterion of whether it is *misbranded* thereunder. Hence, a reasonable standard of compliance therewith, "inhering in the transaction" to which the manufacturer or distributor of the drug is a party, is thereby provided.

Furthermore, under such a construction, the validity of Sec. 502(j) is not open to question as being an unwarranted attempt to interfere in purely local affairs, or to deprive individuals of their inalienable right to medicate themselves. This being so, it is clear that this is the construction of Sec. 502(j) that should be adopted.

Therefore, it is submitted that doubtful constitutionality of Sec. 502(j), when it is construed as the lower Courts herein have construed it, furnishes an additional reason for granting the foregoing petition for a writ of certiorari. This is particularly true in view of the ruling of this Court in *McDermott v. Wisconsin, supra*, to the effect that, when a *misbranding* provision—like Sec. 502(j) —is construed as purely a *labeling* provision the violation of which is to be determined accordingly, it is "clearly *within the powers* of Congress over the facilities of interstate commerce"—with the result that: "This is the *only practical* or *sensible* construction" such a *misbranding* provision.

IV

The record herein does not contain evidence which —as a matter of law—will support a finding that Marmola is *misbranded* under Sec. 502(j), when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly; and this furnishes still another reason for granting the foregoing petition for a writ of certiorari.

Finally, the foregoing petition for a writ of certiorari should be granted because the record in this case does not contain evidence which—as a matter of law—will support a finding that Marmola is *misbranded* under Sec. 502(j), when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly; and this is not only the *proper* but the "*only practical* or *sensible* construction" of a misbranding provision—like Sec. 502(j)—has been decided by this Court in *McDermott v. Wisconsin*, 228 U.S. 115, 130, 131, 132-3 (*supra*, pp. 24, 57). Moreover, this is the required construction (1) in view of the wording of Sec. 502(j), the wording of the other misbranding provisions of the statute in *pari materia* therewith, and its legislative history (*supra*, pp. 25-31, 32-49), and (2) to avoid casting grave doubt upon its constitutionality (*supra*, pp. 50-58).

As has been pointed out (*supra*, pp. 5-10), this case was tried by the Government and decided on the theory that it is only necessary to show that there are certain potential dangers *inherent* in the use of a drug for *self-medication*, in order to prove that it is misbranded under Sec. 502(j). This being the Government's theory it devoted its time to introducing proof of this character; and such proof is immaterial on the question of whether Marmola is *misbranded* under a *labeling* provision—like Sec. 502(j).

Furthermore, the material proof in the record—relying on the testimony of the Government's witnesses alone—discloses that Marmola is labeled according to approved medical standards, as has been pointed out *(supra,* pp. 3-5). Under these circumstances, the evidence to support a finding that Marmola is misbranded under Sec. 502(j) is not only completely lacking, but, if any finding is to be made, it must be that Marmola is properly labeled thereunder.

In other words, this is not merely a case where there is a complete failure of proof to support a finding, but the proof is such as to require a contrary finding—as a matter of law. Therefore, it is submitted that the foregoing petition for a writ of certiorari should be granted for this and the other reasons set forth in the foregoing pages of this brief.

CONCLUSION

It is therefore respectfully submitted that this case is one calling for the exercise by this Court of its supervisory powers, by granting a writ of certiorari and thereafter reviewing and reversing the decision of the Circuit Court of Appeals for the Seventh Circuit, which affirmed the decision of the trial Court herein.

Respectfully submitted,

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Counsel for Petitioner.

APPENDIX

[PUBLIC—No. 717—75TH CONGRESS]

[CHAPTER 675—3D SESSION]

[S. 5]

AN ACT

To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) The term "Territory" means any Territory or possession of the United States, including the District of Columbia and excluding the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the Department of Agriculture of the United States.

(d) The term "Secretary" means the Secretary of Agriculture.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g) The term "drug" means (1) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301 (i), 403 (f), 502 (c), and 602 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

(e) The refusal to permit access to or copying of any record as required by section 703.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (c) (3), which guaranty or undertaking is false.

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404, 406 (b), 504, or 604.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 505, or 704 concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 505, or that such drug complies with the provisions of such section.

INJUNCTION PROCEEDINGS

SEC. 302. (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for

cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes", approved October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (e), (f), (h), (i), and (j).

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 387).

PENALTIES

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act.

SEIZURE

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (2) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case

the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized, and as regards fresh fruits or fresh vegetables, a true copy of the analysis on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

(e) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

HEARING BEFORE REPORT OF CRIMINAL VIOLATION

SEC. 305. Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding

REPORT OF MINOR VIOLATIONS

SEC. 306. Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

PROCEEDINGS IN NAME OF UNITED STATES; PROVISION AS TO SUBPENAS

SEC. 307. All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Notwithstanding the provisions of section 876 of the Revised Statutes, subpenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or

held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided*, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

EMERGENCY PERMIT CONTROL

SEC. 404. (a) Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such

class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

(b) The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

REGULATIONS MAKING EXEMPTIONS

SEC. 405. The Secretary shall promulgate regulations exempting from any labeling requirement of this Act (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in

the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.

CHAPTER V—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopœia and the Homœopathic Pharmacopœia of the United States it shall be subject to the requirements of the United States Pharmacopœia unless it is labeled and offered for sale as a homœopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopœia of the United States and not to those of the United States Pharmacopœia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, quantity, and percentage of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming".

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopœia and the Homœopathic Pharmacopœia of the United States, it shall be subject to the requirements of the United States Pharmacopœia with respect to packaging and labeling unless it is labeled and offered for sale as a homœopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopœia of the United States, and not to those of the United States Pharmacopœia.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

EXEMPTIONS IN CASE OF DRUGS AND DEVICES

SEC. 503. (a) The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), shall if—

(1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and

(2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian,

be exempt from the requirements of section 502 (b) and (e), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of section 502 (d).

CERTIFICATION OF COAL-TAR COLORS FOR DRUGS

SEC. 504. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for

use in drugs for purposes of coloring only and for the certification of batches of such colors, with or without harmless diluents.

NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Secretary by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application.

(d) If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Secretary finds that the facts so require.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his principal place of business, or in the District Court of the United States for the District of Columbia, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the record upon which the order complained of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Secretary shall be final, subject to review as provided in sections 128, 239, and 240 of the Judicial Code, as amended (U. S. C., 1934 ed., title 28, secs. 225, 346, and 347), and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia", approved February 9, 1893 (D. C. Code, title 18, sec. 26). The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) The Secretary shall promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs.

CHAPTER VI—COSMETICS

ADULTERATED COSMETICS

SEC. 601. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604.

MISBRANDED COSMETICS

SEC. 602. A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

REGULATIONS MAKING EXEMPTIONS

SEC. 603. The Secretary shall promulgate regulations exempting from any labeling requirement of this Act cosmetics which are, in accordance with the practice of the trade, to be processed, labeled,

or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS

SEC. 604. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Agriculture shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact

on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. The summons and petition may be served at any place in the United States. The Secretary, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Secretary based his order.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and

shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

EXAMINATIONS AND INVESTIGATIONS

SEC. 702. (a) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department. In the case of food packed in a Territory the Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this Act, the facilities at his disposal will permit of such inspection. For the purposes of this subsection the term "United States" means the States and the District of Columbia.

(b) Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

(c) For purposes of enforcement of this Act, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department of Agriculture duly authorized by the Secretary to make such inspection.

RECORDS OF INTERSTATE SHIPMENT

SEC. 703. For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: *Provided further*, That carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

FACTORY INSPECTION

SEC. 704. For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, after first making request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

PUBLICITY

SEC. 705. (a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

COST OF CERTIFICATION OF COAL-TAR COLORS

SEC. 706. The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

CHAPTER VIII—IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission. This paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under section 2 of the Act of May 26, 1922, as amended (U. S. C., 1934 edition, title 21, sec. 173).

(b) The Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any such article refused

admission, unless such article is exported by the consignee within three months from the date of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter on execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon and on refusing for any cause to return such article or any part thereof to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose, such consignee shall forfeit the full amount of the bond as liquidated damages.

(c) All charges for storage, cartage, and labor on any article which is refused admission or delivery shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignee.

(d) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act.

CHAPTER IX—MISCELLANEOUS

SEPARABILITY CLAUSE

SEC. 901. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

EFFECTIVE DATE AND REPEALS

SEC. 902. (a) This Act shall take effect twelve months after the date of its enactment. The Federal Food and Drugs Act of June 30, 1906, as amended (U. S. C., 1934 ed., title 21, secs. 1–15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: *Provided*, That the provisions of section 701 shall become effective on the enactment of this Act, and thereafter the Secretary is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403 (i) for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401: *Provided further*, That sections 502 (j), 505, and 601 (a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case

of a cosmetic to which the proviso of section 601 (a) relates, such cosmetic shall not, prior to the ninetieth day after such date of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: *Provided further*, That the Act of March 4, 1923 (U. S. C., 1934 ed., title 21, sec. 6; 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 (U. S. C., 1934 ed., title 21, sec. 10; 41 Stat. 271, ch. 26), defining wrapped meats as in package form; and the amendment to the Food and Drugs Act, section 10A, approved August 27, 1935 (U. S. C., 1934 ed., Sup. III, title 21, sec. 14a), shall remain in force and effect and be applicable to the provisions of this Act.

(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended (U. S. C., 1934 ed., title 21, secs. 71–91; 34 Stat. 1260 et seq.).

(c) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the virus, serum, and toxin Act of July 1, 1902 (U. S. C., 1934 ed., title 42, chap. 4); the Filled Cheese Act of June 6, 1896 (U. S. C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923 (U. S. C., 1934 ed., title 21, ch. 3, secs. 61–63); or the Import Milk Act of February 15, 1927 (U. S. C., 1934 ed., title 21, ch. 4, secs. 141–149).

(d) In order to carry out the provisions of this Act which take effect prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended, appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions.

Approved, June 25, 1938.

(10)

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No. 316

In the Supreme Court of the United States

OCTOBER TERM, 1944

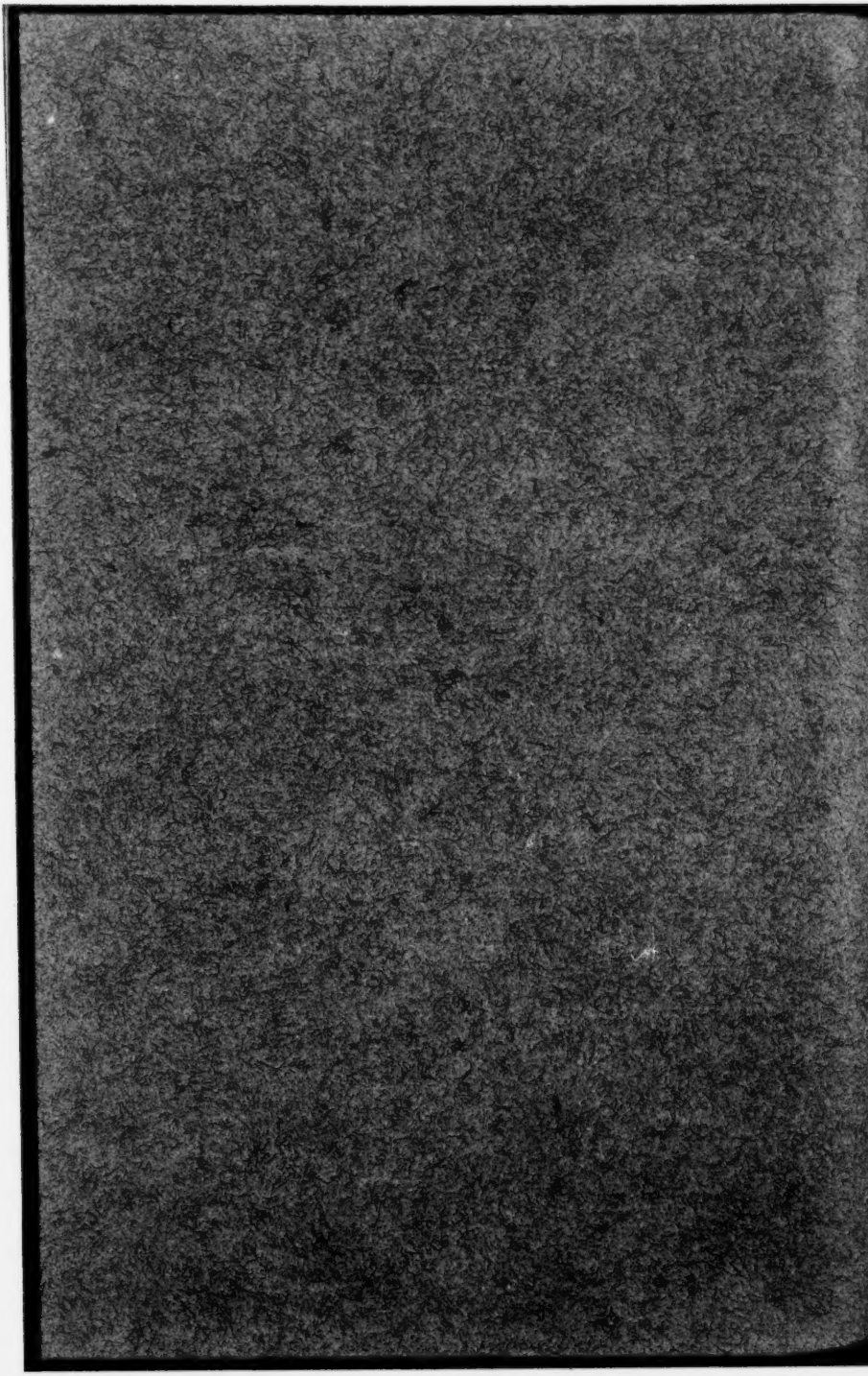
RALADAM COMPANY, AS CLAIMANT OF 62 PACKAGES, MORE OR LESS, OF MARMOLA PRESCRIPTION TABLETS, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION



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OPINIONS BELOW

The opinion of the circuit court of appeals (R. 1353–1359) is reported at 142 F. (2d) 107. The memorandum opinion of the district court (R. 1298–1315) is reported at 48 F. Supp. 878.

JURISDICTION

The judgment of the circuit court of appeals was entered May 4, 1944 (R. 1360). The petition for a writ of certiorari was filed August 3, 1944. The jurisdiction of this Court is invoked under

Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925.

QUESTIONS PRESENTED

The principal questions presented are:

1. Whether a drug is misbranded within the meaning of Section 502 (j) of the Federal Food, Drug, and Cosmetic Act, if, when used in accordance with the directions contained in its labeling, it endangers public health, even though the labeling contains no false or misleading statement.

2. If so, whether the Act is unconstitutional as an interference with the practice of self-medication and as lacking an ascertainable standard for determining when a drug is misbranded.

3. Whether the evidence is sufficient to sustain the findings of the trial judge, concurred in by the circuit court of appeals, that petitioner's product was dangerous to health when used in the dosage, and for the duration of time, prescribed in its labeling, and, therefore, was misbranded under Section 502 (j) of the Federal Food, Drug, and Cosmetic Act.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act (Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. 301 et seq.), provide in part:

* * * * *

> SEC. 304. (a) Any article of food, drug, device, or cometic that is adulterated or misbranded when introduced into or while

in interstate commerce, * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: * * *.

* * * * *

SEC. 502. A drug or device shall be deemed to be misbranded

* * * * *

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

STATEMENT

Proceeding under Section 304 of the Federal Food, Drug, and Cosmetic Act, the United States, on April 11, 1939 (R. 1), filed a libel of information in the District Court of the United States for the Western District of Wisconsin, which was amended on January 8, 1940 (R. 5), against approximately 62 packages of a drug product called Marmola on the ground that it was misbranded under Section 502 (j) of the Act[1] in that it was

[1] The Government also proceeded under Section 502 (a) and 201 (n) of the Act (21 U. S. C. 352 (a) and 321 (n)) and the trial court based the decree of condemnation on these sections as well as on Section 502 (j) (R. 13–26). The circuit court of appeals, however, relied solely upon Section 502 (j) in affirming the decree and petitioner's contentions are directed only to that provision. We, therefore, confine our discussion to Section 502 (j), without, however, waiving reliance on Sections 201 (n) and 502 (a).

dangerous to health when used as prescribed in its labeling (R. 5–7). Petitioner intervened as claimant (R. 3, 5) and the case was tried before the court without a jury.

The Government's libel of information was based on the contention that the seized Marmola Prescription Tablets were dangerous to health because each contained one-half grain of desiccated thyroid (R. 13) [2] and the labeling of the product directed that four tablets be taken each day over a period of 60 to 90 days (R. 9). In support of its claim that the taking of four Marmola tablets each day was dangerous to health, the Government's proof showed that the consumption of two grains of desiccated thyroid of the United States Pharmacopoeia standard constitutes an overdose for many persons. The proof in this respect may be summarized as follows:

When the thyroid gland fails to produce a sufficient amount of thryoxin, which is, or is contained in, the hormone of the thyroid gland, a condition known as hypothyroidism appears. This condition is made evident by such symptoms as thickened and coarsened skin, falling hair, sluggishness of mind and body, a puffy appearance due to a mucoid deposit under the skin, and changes in the

[2] It was stipulated at the trial that "the only ingredient of Marmola Prescription Tablets that is involved in this action is the ½ grain of Desiccated Thyroid contained in each tablet" (R. 19).

blood chemistry, and is accompanied by a depression in the basal metabolic rate. (R. 39, 582–584, 672–674, 690, 700–701, 781, 919.)

If the thyroid gland produces too much of its hormone, a condition known as hyperthyroidism results. This disease is manifested by many signs and symptoms, such as headaches, nausea, vomiting, tachycardia, heart pains, palpitation of the heart, sweating, nervousness, and sleeplessness. In its severe stages, it is usually accompanied by loss of weight. (R. 40, 584, 681, 692, 782–790.) Hyperthyroidism does not cause organic or pathological changes but does induce misfunctions which may be so severe as to cause death (R. 930, 938, 939).

Desiccated thyroid is obtained from the thyroid glands of food animals. When it is administered to a human being it has the same effect as thyroxin spontaneously produced; that is, if a person is deficient in thyroxin the symptoms of hypothyroidism will disappear as the dosage of desiccated thyroid reaches the point where it replaces the deficiency of the thyroxin. If, however, the dosage furnishes more thyroxin than is necessary to maintain the normal functioning of the body, the signs and symptoms of a spontaneous hyperthyroidism appear. (R. 47–48, 421, 587–588, 677–681, 789–790, 806–807, 1163, 1188.)

Persons differ in their tolerance for the drug, and the limit of tolerance can be determined only

by trial and error (R. 90, 247–250, 588–590, 591, 607–608, 637–638, 923–926). All persons who obtain an overdose of desiccated thyroid develop the well-recognized symptoms of hyperthyroidism. Two grains of desiccated thyroid of United States Pharmacopoeia standard [3] constitute overdosage for many persons, that is, on such a daily dosage a considerable proportion, even those who are hypothyroid, will develop symptoms of hyperthyroidism (R. 248, 402–404, 422, 444–446, 470–473, 562–565, 591, 638, 644, 652–653, 662–663, 790–792). These symptoms are not the reactions of allergies or idiosyncrasies (R. 201–213, 496–497).

Moreover, many persons, without realizing it, are suffering from or are extremely susceptible to an illness; that is, such pathological changes may be occurring in their organs, or the reserves of some organs may be so depleted, that these persons cannot withstand extra strain (R. 49–51, 177–180, 484–485). In these persons, the inducing of symptoms of hyperthyroidism accelerates the onset of, or precipitates, the more serious stages of diseases which they may have or to which they may be susceptible or prevents curative measures from being effective (R. 389, 736–738). This is especially true of diabetes (R. 485–495, 497–498) and

[3] The desiccated thyroid used in petitioner's product possesses one and one-half times the potency of that made in accordance with the standard of the United States Pharmacopoeia (R. 18–19; see also R. 1357).

heart disease (R. 559–568, 642–643, 677–679, 692–693). The induced symptoms of hyperthyroidism also contribute to the precipitation of certain functional diseases, such as amenhorrhea, Graves' Disease, and psychoneuroses (R. 788–789, 793–798, 803–804).

On this evidence the trial court found, among other things, that the desiccated thyroid contained in petitioner's tablets produces greater physiological effects than the same quantity prepared according to the standard of the United States Pharmacopoeia (Finding 4, R. 1316), and that (R. 1326):

> 21. The use of two grains of desiccated thyroid daily without medical supervision is dangerous to users.
>
> 22. The Marmola Prescription Tablets, when used as a treatment for obesity in daily dosages of four tablets for the duration of time suggested in the labeling, are dangerous to the health of users.

The trial court concluded as a matter of law (Conclusion 3, R. 1326) that the tablets were misbranded as alleged in the libel of information, and entered a decree of condemnation (R. 1327–1328). On appeal to the Circuit Court of Appeals for the Seventh Circuit the decree was affirmed (R. 1360).

ARGUMENT

1. Contrary to the basic premise of petitioner's entire argument (Pet. 14–17, 24–49), neither the

trial court nor the circuit court of appeals held that Section 502 (j) of the Act is designed to put an end to "the labeling of effective dosages of useful drugs * * * for self-medication" (e. g., Pet. 32) merely because of potential dangers which may be inherent in the drug as such. Rather, the courts held in plain and unambiguous language confined to a single product, petitioner's, that it is misbranded because when used in the manner prescribed, suggested, and recommended in its labeling, it endangers the public health, even though the labeling contains no false or misleading statement and contains the information required by the other sections of the Act.

McDermott v. *Wisconsin*, 228 U. S. 115, 133, upon which petitioner relies (Pet. 14–15, 20–21, 24, 57–59), was not concerned with a provision such as Section 502 (j), and therefore does not aid petitioner in any respect. In that case this Court held invalid a State law the effect of which was to cause the removal of a label that, in accordance with the provisions of the Food and Drugs Act of 1906 (21 U. S. C., 1934 ed., 1 et seq.), had been properly placed on a food shipped in interstate commerce. The reason given by this Court was that "the label is the means of vindication or the basis of punishment in determining the character of the interstate shipment dealt with by Congress." Likewise, in the present case the label must be relied on to ascertain whether the

prescribed use of the product renders it dangerous to the public health.[4]

The construction placed on Section 502 (j) by the courts below accords fully with the design of Congress. The legislative history discloses that, in enacting the section, it was intended to amplify and extend the provisions of the Food and Drugs Act of 1906 so as to close the channels of interstate commerce to a drug product which is dangerous when used according to its labeling even though it does not contain false or misleading statements. This is set forth clearly in Senate Report No. 646, 74th Cong., 1st sess., pp. 7–8, accompanying S. 5, a precursor to the bill which was enacted into law. The report stated:

> Paragraph (b) defines a drug or device as misbranded if it is dangerous to health under the conditions of use prescribed in its labeling or advertising. There are no useful products which would be barred from the market under this provision, since labeling with proper directions for use would remove any worth-while article from this ban. Under the present law, which

[4] Petitioner erroneously conceives Section 502 to be a mislabeling section in the ordinary sense of that term; that is, the label itself must *per se* be false or misleading (see *e. g.*, Pet. 24, 26–28, 37). However, it is evident from those definitions of misbranding contained in the paragraphs of the section following paragraph (a) that a product may be misbranded even though its label is not false or misleading (see Section 502 of the Act as copied at pp. 12–13 of the Appendix to the petition for a writ of certiorari).

contains no provision of this character, there have come on the market a number of dangerous drugs from the use of which many authenticated cases of death and impairment of health have been reported. So long as their labels bore no false or misleading statements, the public could not be protected.

There are certain drugs whose employment is necessary in the treatment of some diseases, which none the less may in very exceptional cases prove harmful to persons to whom they are administered. Their action in such circumstances is comparable to the allergic action of eggs and other common foods, which was discussed in connection with paragraph (a) of section 301. It is not intended that this provision should ban the sale of useful drugs of this kind when they are appropriately labeled. On the other hand, it is not intended that the existence of these drugs shall constitute a cloak under which may hide the manufacturers of unnecessary and dangerous medicaments; or even necessary medicaments with improper or insufficient directions for use that result in the injury of susceptible persons in any considerable number of instances even though most persons could use them with safety. Much criticism has been launched at this provision on the ground that it applies to innocuous drugs for which extravagant therapeutic claims are made and which thus indirectly impair the patient's chance of recovery through his post-

> ponement of proper methods of treatment. The language does not relate to such products. It applies only to potent drugs which are per se harmful unless properly administered.

Petitioner's contention (Pet. 32–39) that the circuit court of appeals construed Section 502 (j) in a manner inconsistent with the other subsections of Section 502 is without merit, for it is based on petitioner's basic misapprehension that the court predicated its decision on the assumption that the subsection prevents the labeling and consumption of desiccated thyroid. It is clear, however, that the court did not so hold. What it did decide was that the drug, under the terms of Section 502 (j), was misbranded because its labeling prescribed a dosage which made the product dangerous to the public health, notwithstanding that it may have complied with the other subsections; and that a drug, to escape being misbranded, must comply with every provision of Section 502. This leads to no inconsistency between the various provisions of the section, which supplement rather than conflict with each other. To offend against any one of the subsections constitutes a misbranding, whether it relates to informative labeling, the form or fill of the container, or dangerous dosage. See *Weeks* v. *United States*, 245 U. S. 618, 621.

2. Petitioner's further contention (Pet. 50–58) that, as construed by the circuit court of appeals, Section 502 (j) is unconstitutional as an unwar-

ranted interference with the practice of self-medication and because it contains no ascertainable standard for determining when a drug is misbranded, is without merit.

As we have pointed out, the decisions below did not deal with the practice of self-medication as such. They related only to a product which, on the basis of the evidence before the courts, was found to be dangerous to the public health when taken in the manner recommended by the manufacturer. There can be no doubt of Congress' power to prohibit the transportation of such an article in interstate commerce.

The power of Congress to regulate commerce "is complete in itself, may be exercised to its utmost extent, and acknowledges no limitations, other than are prescribed in the constitution." *Gibbons* v. *Ogden,* 22 U. S. 1, 196; *United States* v. *Darby,* 312 U. S. 100, 113, 114. The power may be exercised to keep interstate commerce "free from the transportation of illicit or harmful articles, to make such as are injurious to the public health outlaws of such commerce and to bar them from the facilities and privileges thereof." *McDermott* v. *Wisconsin,* 228 U. S. 115, 128. This Court has upheld the right of Congress to close the channels of interstate commerce to a product found to be adulterated notwithstanding the honesty of its label. *United States* v. *Carolene Products Co.,* 304 U. S. 144, 151. And under both the Food and Drugs Act of 1906

and the Federal Food, Drug, and Cosmetic Act, it has been held that the design of the statutes was not confined to a requirement of truthful and informative labeling. *United States* v. *Coca Cola Co.,* 241 U. S. 265, 277, 278; *Federal Security Administrator* v. *Quaker Oats Company,* 318 U. S. 218, 230.

Nor is there wanting a reasonable standard whereby the question of misbranding under the section may be determined Whether a prescribed use of a drug is dangerous to the public health is as susceptible of proof as is the question whether a product contains any added or deleterious substances which may render it injurious to health; and compliance or noncompliance with either standard is equally susceptible of determination. In respect of the latter standard as contained in Section 7 of the Food and Drugs Act of 1906 (21 U. S. C., 1934 ed., 8), this Court found no such difficulty as petitioner perceives. *United States* v. *Coca Cola Co.,* 241 U. S. 265; *United States* v. *Lexington Mill and Elevator Company,* 232 U. S. 399.

3. There is no warrant for petitioner's contention (Pet. 59–60) that the evidence is insufficient to support the findings of the trial judge. The evidence, summarized in the Statement, *supra,* pp. 4–7, shows that two grains per day of desiccated thyroid of United States Pharmacopoeia standard constitute an overdosage for many persons, even those who are hypothyroid; that the daily dosage

of desiccated thyroid prescribed in the labeling of petitioner's product was two grains; and that the desiccated thyroid contained in petitioner's product produces greater physiological effects than a similar amount prepared pursuant to the United States Pharmacopoeia standard. No witness questioned the facts shown by the Government's evidence that an overdosage of desiccated thyroid produces the symptoms of hyperthyroidism and that when such symptoms appear diabetes, tuberculosis, and certain heart diseases are aggravated; that an overdosage sometimes causes amenorrhea; and that excessive thyroid medication heightens and exaggerates existing excited and unstable mental, nervous, and emotional states, which are precipitating factors of Graves' Disease and psychoneuroses. As the court below stated (R. 1358), "We think the evidence such as to justify only the conclusion reached by the trial court. We certainly are not justified in saying that the finding is erroneous as a matter of law. Admittedly, taking four tablets a day, is not dangerous to the health of all users, since tolerance for the drug varies; but the experience of various witnesses, all of whom took tablets according to the directions on the label, as well as the testimony of a number of medical experts, inevitably impel one to the finding that use of the tablets as prescribed is dangerous to the health of the public. * * *"

CONCLUSION

The decision of the circuit court of appeals is correct, the case presents no question of general importance, and there is involved no conflict of decisions. We respectfully submit, therefore, that the petition for a writ of certiorari should be denied.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1944

No. 316

RALADAM COMPANY, as Claimant of 62 Packages, more or less, of Marmola Prescription Tablets,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Respondent.

REPLY BRIEF IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI IN THE ABOVE CAUSE

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REPLY BRIEF IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI IN THE ABOVE CAUSE

The Government's brief in opposition furnishes any additional demonstration needed to show that the petition for a writ of certiorari herein is well grounded and should be granted. Finding itself squarely on the horns of a dilemma when it tries to discuss the fundamental issue in the case, *viz*: whether Sec. 502(j) is purely a *labeling* provision *the violation of which* is to be determined *accordingly*, or a provision designed *to do away with self-medication* with *effective* dosages of *useful*

drugs, like desiccated thyroid, because of the potential dangers *inherent* therein, the Government's brief beclouds and evades this issue by a superficial and sophistic treatment of the real basis and effect of the lower Courts' erroneous decisions and the nature of your petitioner's contentions concerning the same.

The reason why the Government finds itself on the horns of a dilemma in this connection is that it must undertake the insurmountable task of convincing this Court, either of the soundness of the manifestly unsound construction placed on Sec. 502(j) by the lower Courts, or that the record herein contains evidence of actual *misbranding* or *mislabeling*, of which it is entirely devoid.

To elaborate: This case was tried and decided by the lower Courts on the fallacious theory that a drug is *misbranded* within the *meaning* of Sec. 502(j) *unless* it can be taken with safety *in violation of* the directions, instructions, and limitations upon its use set forth in its *labeling*. Conversely, the fact that a drug can be taken *according to* its labeling without danger to health—by recognized standards*—was deemed immaterial by the lower Courts in arriving at their decisions.

In other words, the Marmola *labeling*, in recommending the Marmola dosage of desiccated thyroid "*only* as a treatment for *adult* fat persons whose excess fatness is *caused by hypothyroidism* with accompanying subnormal metabolic rates but who are *otherwise normal and healthy*" (R. 8), is concededly *in accord with approved medical practice*.* Nevertheless, the lower Courts found

*See discussion on pp. 2-5 of the petition herein.

Marmola to be *misbranded* under a *labeling* provision, such as Sec. 502(j), because it cannot be taken with safety by persons *other than those for whom* it is recommended and *to whose use* it is *limited* in the Marmola labeling, as aforesaid. This is the only possible interpretation of decisions holding a *properly labeled* drug, by recognized medical standards, *misbranded* because it cannot be taken indiscriminately with impunity by "the public * * * *at large*" (R. 1358), which includes—of necessity—"the strong, the *weak*, the old, the *young*, the well, and the *sick*" (R. 1313).

Therefore, it is again submitted that the decisions of the lower Courts herein are clearly unsound in failing to construe a *misbranding* provision, such as Sec. 502(j), as purely a *labeling* provision *the violation of which* is to be determined *accordingly*—as required by well-settled principles of statutory construction and the decision of this Court in *McDermott v. Wisconsin*, 228 U. S. 115, 133*, in which is was held that "the *label* is the *means of vindication* and the *basis of punishment*" in determining the issue of *misbranding* under a *labeling* provision, such as Sec. 502(j).

Furthermore, the respective decisions of the lower Courts herein are unsound because they are based on a construction of Sec. 502(j) which is *wholly incompatible* with the *continued existence* of *self-medication* with *effective* dosages of *useful* drugs, like desiccated thyroid, contrary to the intention of Congress—the present protestations of the Government throughout its brief to the

*See discussion on pp. 14-15 of the petition herein and on pp. 24-28 of petitioner's initial brief in support thereof.

contrary notwithstanding.* This is so because, as has just been pointed out, this case was tried and decided on the theory that a drug is "dangerous to health" and misbranded within the meaning of Sec. 502(j) unless it is labeled for use *solely* on a doctor's prescription, *or* can be taken with safety *in mistaken violation* of its labeling, *viz.*, by persons *other than those* for whom it is recommended and *to whose use it is expressly limited* in the labeling thereof.

The Government does not contend that a drug is *misbranded* under a *labeling* provision, such as Sec. 502(j), if it is "dangerous to health" when taken in *willful* or *wanton* disregard of directions, instructions, and limitations on it set forth in its labeling. In other words, not even the Government contends that Sec. 502(j) is designed to protect the public from the dangers of self-medication arising out of their own *willful* misconduct, because such dangers are not *inherent* in self-medication, *per se*. However, the Government does contend that a

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*It is *revealing*, to say the least, that, at the same time the Government is so earnestly insisting, *inside* the courthouse, that no such construction has been placed on Sec. 502(j) by the decisions of the lower Courts herein, it is continually insisting, *outside* the courthouse, that such a construction is required of Sec. 502(j), as evidenced by the following excerpts from the public pronouncements of the Federal Food and Drug Administration:

> "You are familiar with the trade notices issued by this administration on August 26 and September 8, 1938, relating to the distribution of preparations containing aminopyrine," etc. "In brief, these notices announced the Administration's opinion that such drugs, if distributed so that they would be used by the general public without *appropriate medical supervision*, would be regarded as *misbranded* in violation of *Section 502(j)* of the Food, Drug, and Cosmetic Act.
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> * * * * *
>
> "It should be understood that this principle applies *not only to the specific drugs* which were dealt with in the trade announcements referred to above, *but is applicable to all drugs* which *may be* dangerous to health unless used under *appropriate supervision*" (*Trade Communication No. 4* C. C. H. Food Drug, Cosmetic Law Service, par. 10,160.01, pp. 10,234-35.) [Italics ours.]

(*Continued on next page*)

drug is *misbranded* within the *meaning* of Sec. 502(j), if it is "dangerous to health" when taken in *unwitting* or *mistaken* violation of its *labeling*.

It is the *inherent* dangers of *self-medication*, such as these, with which the lower Courts herein are either expressly or implicitly concerned in their decisions (R. 1313, 1314, 1357-8). They arise from the possibility of a layman untrained in medical science, making an honest mistake in self-diagnosis—as a result of which he gets into difficulty through taking a drug in *mistaken* violation of one or more of the directions, instructions, or limitations upon its use set forth in its labeling.

Clearly, no form of labeling *for self-medication* can be devised to eliminate *such* dangers. By the very nature of things, they are *inherent*, to a varying degree, in *all* self-medication with *effective* dosages of useful drugs, like

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"The administration has received numerous requests from drug manufacturers, retail and wholesale drug associations, and others, for a list of those drug products which it considers dangerous *when sold otherwise than on the prescription of a physician*, dentist, or veterinarian licensed by law to administer drugs.

"* * * Obviously, *it is impossible* to list *all drugs* which *may be* dangerous * * *. As examples of drugs which *are considered dangerous* when distributed for use *otherwise than on prescription*, the following have been mentioned:" [The Food and Drug Administration then proceeds to list some 28 drugs, *including thyroid*, as examples of those which it considers dangerous in *any effective* dosage, "when distributed for use *otherwise* than on prescription."] *(Trade Communication No. 361*, C. C. H. Food Drug Cosmetic Law Service, par. 10,201, p. 10,297.) [Italics ours.]

"The law prohibits the unrestricted sale, within its jurisdiction, of drugs which constitute useful therapeutic agents in the hands of qualified physicians but are too dangerous for use in self-medication. * * * The regulations permit the sale of such drugs on prescription and require the label to bear the legend 'Caution: To be used only by or on the prescription of a physician,' but prohibit general retail distribution of them. * * *" *(Annual Reports of the Food and Drug Administration for 1941-42 and 1942-43.)*

desiccated thyroid;* and, being dangers of self-medication, *per se*, they can only be eliminated by doing away with it entirely—except in dosages which are *ineffective* and, therefore, harmless.

Despite what some people may think of the desirability of such a program from a public health standpoint, the fundamental trouble with it is that the Federal Food, Drug and Cosmetic Act is not designed to accomplish any such result, as fully demonstrated on pages 24-49 of petitioner's initial brief; and, under our system of government, it is beyond the function of the judicial branch to revise legislative enactments, even though it may be felt that the public health or welfare will be better served by so doing.

As has been pointed out on pages 34-37 of petitioner's initial brief, Secs. 502(e) and 502(f) make express provision for the *labeling* of effective dosages of *dessicated thyroid* and other useful drugs *for self-medication*, in spite of the recognized potential dangers *inherent* in their use for such purposes. On pages 38-39 of petitioner's initial brief it is demonstrated that Sec. 502(j) cannot be construed to prevent self-medication with *any dosage* of desiccated thyroid which continues to be available for use on a doctor's prescription.** On pages 40-49 of the same brief, the discussion of the legislative history of the Act clearly reveals that it "is not intended to restrict *in any way* the *availability* of drugs for self-medication" (see page 47 of petitioner's initial brief); and all this clearly contemplates the continuance of self-medication with *effective* dosages of *all* useful drugs, including desiccated thyroid.

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*See discussion on pp. 10-11 of the petition herein and on pp. 29-30 of petitioner's initial brief in support thereof.

**According to the testimony of the Government's own witnesses, the Marmola *dosage* of desiccated thyroid is "widely used" by the medical profession in the treatment of the very same condition for which Marmola is recommended in its labeling. In fact, its use for such purpose is considered "*indispensible* at the present time" (see discussion on pp. 3-4 of the petition herein).

Under these circumstances, it is submitted that the construction placed on Sec. 502(j) by the lower Courts herein is manifestly unsound, because it can have no other effect than to make desiccated thyroid and *all* other useful drugs *unavailable* for *self-medication*, in *effective** dosages. Such a construction is not only contrary to the *intended purpose* of the statute, but will cast grave doubt on its constitutionality, as pointed out on pages 50-8 of petitioner's initial brief. Hence, it is clear that the petition for a writ of certiorari herein should be granted.

Finally, if anything further is needed to demonstrate conclusively the unsound character of the construction placed on Sec. 502(j) by the lower Courts herein, it is the lengthy quotation from a Senate Report forming part of the legislative history of the Act set forth on pages 9-11 of the Government's brief in opposition. For example, in this Senate Report—relied on by the Government to show how Congress intended Sec. 502(j) to be construed—it is stated:

> "There are certain drugs whose employment is *necessary in the treatment of some diseases*, which none the less may in very *exceptional cases* prove *harmful* to persons to whom they are administered. * * *" (Italics ours.)

As has been pointed out in the discussion on pages 3-5 of the petition herein, it is fully established by the Government's witnesses alone that desiccated thyroid is considered by the medical profession to be "necessary in the treatment" of obesity caused or contributed to by, or associated with, hypothyroidism; and, more important still

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*It is conceded by the Government, through the testimony of Dr. Brimmer, Senior Medical Officer of the Federal Food and Drug Administration, that these *same* potential dangers *inherent* in self-medication with the Marmola dosage of desiccated thyroid are *inherent* in self-medication with *any effective dosage* of all *useful* drugs known to *materia medica* (R. 1216, 1236). Other expert witnesses called by the Government testified to the same effect (R. 203-4, 440-1, 712), and none of the Government witnesses testified to the contrary. Also, see discussion on pages 10-11 and 29-30 of petitioner's initial brief.

from the standpoint of whether Marmola is misbranded under Sec. 502(j), desiccated thyroid is "widely used" by the medical profession for such treatment, in the *same average dosage* as that recommended in the Marmola labeling. Likewise, the direction in the Marmola labeling to stop the medication if any unpleasant effects are experienced and then resume at one-half the former dosage after they have disappeared (R. 9) is in accord with approved medical practice (see discussion in second footnote on page 4 of the petition herein).

That self-medication with desiccated thyroid in the Marmola dosage "may in very exceptional cases prove *harmful,*" is conceded. The Marmola labeling expressly advises the prospective consumer of this fact (R. 9). However, this does not render a drug "dangerous to health" within the *meaning* of Sec. 502(j), according to the legislative history of the Act upon which the Government relies as furnishing the key to the correct construction of Sec. 502(j).

The same Senate Report further defines the *intended scope* and *application* of Sec. 502(j) as follows:

> "* * * There are *no useful products* which would be barred from the market under this provision, since *labeling* with *proper directions* for use would *remove* any worth-while article from this ban. * * *
>
> "* * * It is not intended that this provision should ban the sale of *useful* drugs of *this kind* when they are *appropriately labeled.* * * *" (Italics ours.)

The Government's proof establishes that desiccated thyroid in the Marmola dosage is not only a "worthwhile" and "*useful* drug" in the treatment of the *sole* condition for which Marmola is recommended, but "indispensable" (R. 902). Moreover, the Government's witnesses have established that its labeling contains "*proper* directions for use," according to *recognized medical*

standards, as has been pointed out on pages 2-5 of the petition herein.

The Government's *only* real claim of *misbranding* under Sec. 502(j) is that Marmola may be "dangerous to health" if a person *unwittingly* takes it *in violation of* the labeled "directions for use" due to a mistake in self-diagnosis.* The trouble with such a claim is that it is clearly immaterial because the Marmola labeling contains "proper directions for use," by *recognized medical standards*, which *removes it* from the "ban" of Sec. 502(j), according to the Senate Report relied on by the Government to show the true meaning and construction thereof.

In view of the foregoing, it is again submitted that this is a case in which this Court should grant the writ of certiorari prayed for, in order to review and correct the patently unsound judgments of the lower Courts herein. It is realized that the Court may not be overly prejudiced

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*It is true that the Government—now that it fully appreciates the fatal deficiencies in its case—also makes a half-hearted attempt to convince this Court, by furnishing a few misleading record references on page 6 of its brief, that Marmola is "dangerous to health," *by recognized medical standards*, when taken *according to* "the directions for use" in its labeling. An analysis of the parts of the record to which the Court's attention is directed by these references further illustrates how devoid the record in this case is of any such proof.

For example, the first of these references (R. 248) directs attention to testimony by the Government's expert, Dr. Newburgh, that: "I know that the dose [of desiccated thyroid] that is *commonly employed, two grains*, will harm *some* individuals." Conceding that this is so, it clearly does not constitute proof that Marmola is harmful to the *only* persons *for whom* it is recommended in its *labeling, viz.*, adult hypothyroid obese persons who are otherwise normal and healthy; and, in addition, the fact that a drug which is properly labeled—by recognized medical standards—"will harm *some* individuals," does not bring it within *the ban* of Sec. 502(j), according to its legislative history relied on by the Government, as disclosing its *intended scope*, which states that "appropriately labeled" drugs are meant to be excluded "from *this ban*," although they occasionally may "prove harmful."

What has just been said regarding the immateriality of Dr. Newburgh's testimony will be found, on examination, to be equally true of the expert testimony of Dr. Boggs (R. 422), Dr. Kurtz (R. 562-5), Dr. Haines (R. 591), Dr. Brussock (R. 638), and Dr. Gunderson (R. 644). Suffice it to

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in favor of continued self-medication with Marmola, and that sometimes "hard cases make bad law," as the old saying goes. However, no precedent has been found for recognizing this saying as a rule of decision in this Court. Congress having passed a statute which "is not intended to restrict *in any way* the *availability* of drugs for self-medication," when they are "appropriately labeled" for such purpose, and Marmola having been established by the testimony of the Government's own witnesses in this case to be "appropriately labeled"—by recognized medical standards—it is clear that the judgment of the lower Courts that Marmola is *misbranded* under Sec. 502(j), regardless of the *propriety* of its *labeling*, has no basis—as a matter of law—and should be reversed.

Respectfully submitted,

ROCKWELL T. GUST AND
DAVID A. HOWELL,
Counsel for Petitioner.

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say that none of the Government witnesses testified, or was asked to testify, that Marmola is "dangerous to health"—*by recognized medical standards*—when taken by the persons *for whom* it is recommended in its *labeling*, according to the other directions and instructions therein set forth. The reason for this is not hard to find. The testimony of these very same witnesses is *all* to the contrary, as has been pointed out on pages 2-5 of the petition herein.

Equally immaterial on the real issues in this case is the testimony of or concerning the lay witnesses, Mrs. Skardarasy (R. 402-4), Mrs. Hansen (R. 444-6), Ophelia Ridgeway (R. 470-3 and 790-2), Florence L. Ruth (R. 652-3), and Estelle Kimoteck (R. 662-3). None of these persons was shown to be one of those *for whom* Marmola is recommended in its labeling, *viz.*, an adult hypothyroid obese person who was otherwise normal and healthy, when she started the medication. Not only did the testimony of some of the witnesses disclose the contrary, but it invariably disclosed that they had violated one or more of the "directions for use," in taking Marmola (see discussion in footnote on p. 6 of the petition herein); and—speaking of "exceptional cases" of harm falling outside the "ban" of the statute—these were the only examples which the Government could produce of alleged harm from *even* the *indiscriminate* use of a product of which more than 20,000,000 packages had been sold over a period of thirty years (R. 18), although the Government advertised extensively for witnesses in medical journals, searched hospital records and interviewed doctors throughout the United States in this connection (R. 756 and 1252-5).